

US3032172 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:50:29

All time stamps listed in this document are displayed in GMT

US3032172

**Form: Participant Creation**

**Data signed:** (b) (4) 28 Sep 2020 17:22:02

**Generated On: 11 Aug 2021 21:50:29**

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[Participant ID](#)

US3032172

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

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US3032172

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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US3032172

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3032172

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

Date of Informed Consent (*dd MMM yyyy*) 10 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

US3032172

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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Did the participant meet all eligibility criteria?

Yes

No

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US3032172

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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Were any significant conditions reported?

Yes

No

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US3032172

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 18:06:47

Generated On: 11 Aug 2021 21:50:29

Condition	ARTHRALGIA- BILATERAL KNEES
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)	_____

US3032172

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 18:06:47

Generated On: 11 Aug 2021 21:50:29

Condition	CHRONIC ITCHING- BILATERAL HANDS
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032172

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 18:06:47

Generated On: 11 Aug 2021 21:50:29

Condition	LOW TESTOSTERONE
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3032172

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 18:06:47

Generated On: 11 Aug 2021 21:50:29

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

US3032172

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 18:06:47

Generated On: 11 Aug 2021 21:50:29

Condition	SEASONAL ALLERGIES
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)	_____

US3032172

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 18:06:47

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:30:47

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:08 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:08
Height ( <i>xxx.x</i> )	177.8 cm
Weight ( <i>xxx.x</i> )	96.6 kg
BMI ( <i>xxx.x</i> )	30.55720 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)	_____

US3032172

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 21:36:59

Generated On: 11 Aug 2021 21:50:29

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

10 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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US3032172

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes  No

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**Specify**

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

<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) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 10 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) 02 Nov 2020 22:05:33

Generated On: 11 Aug 2021 21:50:29

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 102685

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) 08 Dec 2020 19:47:51

Generated On: 11 Aug 2021 21:50:29

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Height	ND - Not Done
Weight	ND - Not Done

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US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Dec 2020 19:47:51

Generated On: 11 Aug 2021 21:50:29

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> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:08 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:08
Temperature ( <i>xxx.x</i> )	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	89 mmHg
Diastolic Blood Pressure units	MMHG

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Dec 2020 19:47:51

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:58 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 14:58
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	60 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG

US3032172

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 21:36:59

Generated On: 11 Aug 2021 21:50:29

---

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.*

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 14:26 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 14:26

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

What was the frequency of the study treatment dosing? ONCE

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

US3032172

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 10 AUG 2020

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Collection time (*00:00-23:59*) 13:50 (24 HR)

---

Collection date and time (derived) 10 AUG 2020 13:50

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US3032172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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Collection date ( <i>dd MMM yyyy</i> )			10 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	13:34	10 AUG 2020 13:34
Nasopharyngeal Swab 2	No		

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US3032172

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.2 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes  No

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

PC Time Stamp 10 AUG 2020 14:59

PC Open Date & Time 10 AUG 2020 14:46

PC Close Date & Time 10 AUG 2020 17:16

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**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 96.8 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes  No

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

PC Time Stamp	10 AUG 2020 18:12
PC Open Date & Time	10 AUG 2020 18:11
PC Close Date & Time	11 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**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	11 AUG 2020 12:30
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °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	12 AUG 2020 15:12
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**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	97.9 °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	13 AUG 2020 12:26
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**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	96.9 °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	14 AUG 2020 14:01
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**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	97.3 °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	15 AUG 2020 12:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 98.5 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes  No

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

PC Time Stamp	16 AUG 2020 12:01
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**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	10 AUG 2020 15:00
PC Open Date & Time	10 AUG 2020 14:46
PC Close Date & Time	10 AUG 2020 17:16

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**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

10 AUG 2020 18:13

PC Open Date & Time

10 AUG 2020 18:11

PC Close Date & Time

11 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**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

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

11 AUG 2020 12:30

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**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

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

12 AUG 2020 15:12

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**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	13 AUG 2020 12:26
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**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

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

14 AUG 2020 14:02

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**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

15 AUG 2020 12:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**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

16 AUG 2020 12:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**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

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

No   
Yes

---

PC Time stamp	10 AUG 2020 15:00
PC Open Date & Time	10 AUG 2020 14:46
PC Close Date & Time	10 AUG 2020 17:16

---

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**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

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

No

Yes

---

PC Time stamp	10 AUG 2020 18:12
PC Open Date & Time	10 AUG 2020 18:11
PC Close Date & Time	11 AUG 2020 11:59

---

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**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

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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Yes

---

PC Time stamp	11 AUG 2020 12:31
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

---

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**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

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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	Yes <input type="checkbox"/>
PC Time stamp	12 AUG 2020 15:13
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

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US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**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

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

---

	Yes <input type="checkbox"/>
PC Time stamp	13 AUG 2020 12:27
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

---

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**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

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

---

	Yes <input type="checkbox"/>
PC Time stamp	14 AUG 2020 14:02
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

---

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**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

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

---

	Yes <input type="checkbox"/>
PC Time stamp	15 AUG 2020 12:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

---

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**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

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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	Yes <input type="checkbox"/>
PC Time stamp	16 AUG 2020 12:01
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

---

US3032172

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 AUG 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3032172

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:22:05

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3032172

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:22:05

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3032172

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

---

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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> )	21 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	12:25 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 12:25
Temperature ( <i>xxx.x</i> )	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	63 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

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	

US3032172

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

21 SEP 2020

---

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

---

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

Was study treatment given? Yes   
No

If No, reason not given

Participant declined due to Adverse Event   
Physician withheld dose due to Adverse Event   
Death   
Lost To Follow-Up   
Physician Decision   
Pregnancy   
Protocol Deviation   
Study Terminated by Sponsor   
Withdrawal of Consent by Participant   
Confirmed COVID-19   
Other

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

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

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

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

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

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

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

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

US3032172

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 21 SEP 2020

---

Collection time (*00:00-23:59*) 13:08 (24 HR)

---

Collection date and time (derived) 21 SEP 2020 13:08

---

US3032172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

---

Collection date ( <i>dd MMM yyyy</i> )			21 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:43	21 SEP 2020 12:43
Nasopharyngeal Swab 2	No		

---

US3032172

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:22:38

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 28 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3032172

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

*If Contact Not Made, please provide Comments*

US3032172

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

---

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*

---

---

US3032172

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

---

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

---

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) 19 OCT 2020

Time of assessment (00:00-23:59) 10:17 (24 HR)

Vital Signs Date and Time (derived) 19 OCT 2020 10:17

Temperature (xxx.x) 37.1 C

Route of measurement Oral   
Axillary   
Other

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

Pulse (xxx) 84 beats/min

Pulse units BPM

Respiratory Rate (xxx) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 139 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 75 mmHg

Diastolic Blood Pressure units MMHG

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

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

US3032172

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

19 OCT 2020

---

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

---

US3032172

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 OCT 2020

---

Collection time (*00:00-23:59*) 10:25 (24 HR)

---

Collection date and time (derived) 19 OCT 2020 10:25

---

US3032172

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 OCT 2020 12:00:54
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 12:00:54
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

<b>TIMEPOINT</b>	<b>DAY 78</b>
Have 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 OCT 2020 07:04:55
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 92
Have 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	07 NOV 2020 07:43:05
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 99
Have 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 NOV 2020 07:49:05
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 21 NOV 2020 08:13:57

Patient Cloud Open Date & Time 18 NOV 2020 00:01

Patient Cloud Close Date & Time 22 NOV 2020 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	26 NOV 2020 14:44:14
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	02 DEC 2020 06:05:32
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	12 DEC 2020 17:59:19
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 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	16 DEC 2020 06:35:41
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	23 DEC 2020 06:04:43
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	30 DEC 2020 05:53:13
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	06 JAN 2021 09:18:01
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	13 JAN 2021 06:21:21
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	20 JAN 2021 06:18:24
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 27 JAN 2021 06:15:02

Patient Cloud Open Date & Time 27 JAN 2021 00:01

Patient Cloud Close Date & Time 31 JAN 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	03 FEB 2021 06:32:33
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 06:17:46
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	17 FEB 2021 05:37:34
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 11:59:19
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 06 MAR 2021 18:02:57

Patient Cloud Open Date & Time 03 MAR 2021 00:01

Patient Cloud Close Date & Time 07 MAR 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 02:16:53
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 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	17 MAR 2021 05:58:10
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 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 MAR 2021 07:02:46
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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	31 MAR 2021 06:19:32
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message 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	07 APR 2021 05:28:47
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 12:15:02
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 <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	21 APR 2021 05:31:21
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

Date and time of submission 28 APR 2021 05:36:36

Patient Cloud Open Date & Time 28 APR 2021 00:01

Patient Cloud Close Date & Time 02 MAY 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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](#)

26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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23 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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

**US3032172**

**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>	21 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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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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01 AUG 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

**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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04 AUG 2021 00:01

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08 AUG 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

**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>	11 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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°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

**US3032172**

**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](#)

18 AUG 2021 00:01

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22 AUG 2021 23:59

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US3032172

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**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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25 AUG 2021 00:01

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29 AUG 2021 23:59

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US3032172

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**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°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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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01 SEP 2021 00:01

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05 SEP 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

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**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

**US3032172**

**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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08 SEP 2021 00:01

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12 SEP 2021 23:59

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US3032172

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Form: Safety Follow Up Diary

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**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°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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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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 SEP 2021 00:01

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19 SEP 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
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US3032172

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Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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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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<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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 17 OCT 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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>	10 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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>	17 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 NOV 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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 JAN 2022 00:01

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09 JAN 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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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>	12 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JAN 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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

**US3032172**

**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](#)

19 JAN 2022 00:01

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23 JAN 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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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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26 JAN 2022 00:01

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30 JAN 2022 23:59

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**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°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

**US3032172**

**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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02 FEB 2022 00:01

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06 FEB 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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

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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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<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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3032172**

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**Generated On: 11 Aug 2021 21:50:29**

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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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 FEB 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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

**US3032172**

**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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[Patient Cloud Open Date & Time](#) 23 FEB 2022 00:01

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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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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02 MAR 2022 00:01

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06 MAR 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

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09 MAR 2022 00:01

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13 MAR 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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

**US3032172**

**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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16 MAR 2022 00:01

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20 MAR 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

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27 MAR 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

**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](#)

13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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

**US3032172**

**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>	27 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 MAY 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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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](#)

11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

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26 JUN 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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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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10 JUL 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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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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17 JUL 2022 23:59

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Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3032172**

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**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

**US3032172**

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**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

**US3032172**

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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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07 AUG 2022 23:59

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US3032172

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**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°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

**US3032172**

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**Generated On: 11 Aug 2021 21:50:29**

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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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14 AUG 2022 23:59

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Generated On: 11 Aug 2021 21:50:29

**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°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

**US3032172**

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 23:59

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US3032172

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Form: Safety Follow Up Diary

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**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

**US3032172**

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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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28 AUG 2022 23:59

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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31 AUG 2022 00:01

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04 SEP 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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Form: Safety Follow Up Diary

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**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

**US3032172**

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**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59

---

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	28 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 OCT 2022 23:59

---

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#) 05 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#) 09 OCT 2022 23:59

---

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

---

US3032172

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:50:29

---

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		06 MAR 2021 18:03:07

---

US3032172

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Dec 2020 19:47:51

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 NOV 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3032172

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Dec 2020 19:47:51

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Dec 2020 15:54:01

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 DEC 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3032172

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Dec 2020 15:54:01

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 JAN 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3032172

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:35:52

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:35:52

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 15 FEB 2021

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3032172

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:35:52

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 19 MAR 2021

---

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

---

Folder OID VISIT4

---

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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) \_\_\_\_\_

US3032172

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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.*

---

US3032172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

Was the sample collected? Yes   
No

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

Collection time (00:00-23:59) \_\_\_\_\_

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

US3032172

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 18:22:01

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 APR 2021

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3032172

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 18:22:01

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

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* \_\_\_\_\_

**US3032172**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 17 Nov 2020 15:50:59

Generated On: 11 Aug 2021 21:50:29

---

Date of Contact	01 SEP 2020
Time of Contact	12:07
Date and Time of Contact (derived)	01 SEP 2020 12:07
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"/>

---

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

Symptom Day

Day 1	<input checked="" 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 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"/>

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

	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 AUG 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done

---

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

---

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

---

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

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

---

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

	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 SEP 2020
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	99.4 F

---

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

---

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

---

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

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

---

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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"/>

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

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---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	02 SEP 2020
------	-------------

---

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

---

O2 Saturation	96 %
---------------	------

---

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

---

Temperature	100.4 F
-------------	---------

---

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

---

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

---

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

---

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

---

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---

Not Done

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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---

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

---

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

---

Nausea

None

Mild

Moderate

Severe

Not Done

---

Vomiting

None

Mild

Moderate

Severe

Not Done

---

Diarrhea

None

Mild

Moderate

Severe

Not Done

---

Sore Throat

None

Mild

Moderate

Severe

Not Done

---

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	03 SEP 2020
------	-------------

---

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

---

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

---

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

---

Temperature	98.6 F
-------------	--------

---

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

---

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

---

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

---

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Form: Symptom Log (4)

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	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input 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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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---

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

---

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

---

Nausea

None

Mild

Moderate

Severe

Not Done

---

Vomiting

None

Mild

Moderate

Severe

Not Done

---

Diarrhea

None

Mild

Moderate

Severe

Not Done

---

Sore Throat

None

Mild

Moderate

Severe

Not Done

---

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	04 SEP 2020
------	-------------

---

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

---

O2 Saturation	100 %
---------------	-------

---

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

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

---

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

---

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---

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

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Form: Symptom Log (5)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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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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Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	05 SEP 2020
------	-------------

---

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

---

O2 Saturation	96 %
---------------	------

---

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

---

Temperature	97.8 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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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	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input 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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Form: Symptom Log (6)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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---

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

---

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

---

Nausea

None

Mild

Moderate

Severe

Not Done

---

Vomiting

None

Mild

Moderate

Severe

Not Done

---

Diarrhea

None

Mild

Moderate

Severe

Not Done

---

Sore Throat

None

Mild

Moderate

Severe

Not Done

---

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Form: Symptom Log (7)

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---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	06 SEP 2020
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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---

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

US3032172

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Form: Symptom Log (7)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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---

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

---

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

---

Nausea

None

Mild

Moderate

Severe

Not Done

---

Vomiting

None

Mild

Moderate

Severe

Not Done

---

Diarrhea

None

Mild

Moderate

Severe

Not Done

---

Sore Throat

None

Mild

Moderate

Severe

Not Done

---

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:36:10

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---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	07 SEP 2020
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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 01 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input 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 01 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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"/>

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

	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 SEP 2020
------	-------------

---

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

---

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

---

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

---

Temperature	97.1 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

---

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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 01 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

	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 SEP 2020
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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

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EAB) (1725)

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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 01 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

	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 SEP 2020
------	-------------

---

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

---

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

---

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

---

Temperature	97.5 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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 01 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

---

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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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Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

	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 SEP 2020
------	-------------

---

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

---

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

---

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

---

Temperature	97.8 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

---

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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"/>

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

	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 SEP 2020
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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

---

Temperature	97.3 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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

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EAB) (1725)

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

---

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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"/>

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

	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 SEP 2020
------	-------------

---

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

---

O2 Saturation	100 %
---------------	-------

---

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

---

Temperature	97.6 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

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

---

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

---

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

---

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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"/>

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	14 SEP 2020
------	-------------

---

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

---

O2 Saturation	100 %
---------------	-------

---

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

---

Temperature	97.8 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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 type="checkbox"/>
Day 16	<input checked="" 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"/>

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	15 SEP 2020
------	-------------

---

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

---

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

---

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

---

Temperature	96.8 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)

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 17 Nov 2020 15:50:57

Generated On: 11 Aug 2021 21:50:29

Date of Visit 1 SEP 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 1 SEP 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) 1

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 17 Nov 2020 15:50:59

Generated On: 11 Aug 2021 21:50:29

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

If Yes, provide:

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

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

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

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

If Yes, provide:

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

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

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

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

If Yes, provide:

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

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

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

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

If Yes, provide:

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

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

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

Did the subject have Respiratory failure? Yes   
No

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

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

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 17 Nov 2020 15:50:59

Generated On: 11 Aug 2021 21:50:29

---

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

**Ventilator Support:**

High-Flow Oxygen? Yes   
No

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

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

Non-Invasive Ventilation? Yes   
No

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

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

Mechanical Ventilation? Yes   
No

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

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

ECMO? Yes   
No

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

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

**Evidence of Shock:**

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

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

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

Evidence of Shock Requires Vasopressors Yes   
No

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

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

Acute Renal Dysfunction? Yes   
No

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 17 Nov 2020 15:50:59

Generated On: 11 Aug 2021 21:50:29

Hepatic Dysfunction? Yes   
No

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

Neurologic Dysfunction? Yes   
No

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

**Evidence of Pneumonia:**

Clinical Evidence Yes   
No

Date of Assessment \_\_\_\_\_

Radiographical Evidence Yes   
No

Date of Assessment \_\_\_\_\_

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

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

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

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Sep 2020 17:22:04

Generated On: 11 Aug 2021 21:50:29

---

[Generate Next COVID-19 Assessment](#)

Yes

No

---

US3032172

Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 22 Oct 2020 14:49:54

Generated On: 11 Aug 2021 21:50:29

---

[Generate Next COVID-19 Assessment](#)

Yes   
No

---

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	3 SEP 2020
Day 5	Yes	5 SEP 2020
Day 7	Yes	7 SEP 2020
Day 9	Yes	9 SEP 2020
Day 14	Yes	14 SEP 2020
Day 21	Yes	21 SEP 2020
Day 28	Yes	05 OCT 2020

US3032172

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:22:05

Generated On: 11 Aug 2021 21:50:29

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

---

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Sep 2020 17:22:05

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	1 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:30 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 14:30
Height ( <i>xxx.x</i> )	177.8 cm
Weight ( <i>xxx.x</i> )	96.6 kg
Temperature ( <i>xxx.x</i> )	37.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	82 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3032172

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:22:05

Generated On: 11 Aug 2021 21:50:29

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

1 SEP 2020

---

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

---

US3032172

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 28 Sep 2020 17:22:05

Generated On: 11 Aug 2021 21:50:29

---

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

Yes

No

NA (COVID-19 Negative)

---

Date of Collection

1 SEP 2020

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 15:30:46

Generated On: 11 Aug 2021 21:50:29

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

---

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:30:46

Generated On: 11 Aug 2021 21:50:29

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> )	12:57 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 12:57
Height ( <i>xxx.x</i> )	177.8 cm
Weight ( <i>xxx.x</i> )	96.4 kg
Temperature ( <i>xxx.x</i> )	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 15:30:45

Generated On: 11 Aug 2021 21:50:29

---

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.*

---

US3032172

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 08 Oct 2020 15:30:45

Generated On: 11 Aug 2021 21:50:29

---

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
	NA (COVID-19 Negative) <input type="radio"/>

---

Date of Collection	5 OCT 2020
--------------------	------------

---

**US3032172**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

---

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 \_\_\_\_\_

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

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.*

US3032172

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:50:29

---

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

---

Date of Collection \_\_\_\_\_

---

**US3032172**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

---

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 \_\_\_\_\_

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

---

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.*

---

US3032172

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:50:29

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

Yes

No

NA (COVID-19 Negative)

Date of Collection \_\_\_\_\_

US3032172

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

Form: Visit Date

Data signed: (b) (4) 18 Jan 2021 19:28:14

Generated On: 11 Aug 2021 21:50:29

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 9 JAN 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

US3032172

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Date of updated informed consent ( <i>dd MMM yyyy</i> )	9 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	9 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3032172

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Jan 2021 19:28:14

Generated On: 11 Aug 2021 21:50:29

---

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

---

---

US3032172

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Jan 2021 19:28:14

Generated On: 11 Aug 2021 21:50:29

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)	9 JAN 2021
Time of assessment (00:00-23:59)	11:26 (24 HR)
Vital Signs Date and Time (derived)	9 JAN 2021 11:26
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3032172

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Jan 2021 19:28:14

Generated On: 11 Aug 2021 21:50:29

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)	9 JAN 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	9 JAN 2021 13:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3032172

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

Form: Physical Examination

Data signed: (b) (4) 18 Jan 2021 19:28:14

Generated On: 11 Aug 2021 21:50:29

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

9 JAN 2021

---

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

---

US3032172

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

Form: Exposure

Data signed: (b) (4) 18 Jan 2021 19:28:14

Generated On: 11 Aug 2021 21:50:29

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) 9 JAN 2021

What was the treatment time? (00:00-23:59) 12:36 (24 HR)

Treatment Date and Time (derived) 9 JAN 2021 12:36

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

US3032172

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Jan 2021 19:28:14

Generated On: 11 Aug 2021 21:50:29

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 9 JAN 2021

---

Collection time (*00:00-23:59*) 11:04 (24 HR)

---

Collection date and time (derived) 9 JAN 2021 11:04

---

US3032172

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Jan 2021 19:28:14

Generated On: 11 Aug 2021 21:50:29

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 9 JAN 2021

---

Collection time (*00:00 - 23:59*) 11:10

---

Collection Date and Time (derived) 9 JAN 2021 11:10

---

US3032172

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

Form: Continuing

Data signed: (b) (4) 18 Jan 2021 19:28:14

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:55:23

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 JAN 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3032172

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:55:23

Generated On: 11 Aug 2021 21:50:29

---

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

---

US3032172

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:55:23

Generated On: 11 Aug 2021 21:50:29

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

---

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:55:23

Generated On: 11 Aug 2021 21:50:29

---

Height	ND - Not Done
Weight	ND - Not Done

---

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:55:23

Generated On: 11 Aug 2021 21:50:29

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> )	9 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	11:16 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 11:16
Temperature ( <i>xxx.x</i> )	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	64 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	85 mmHg
Diastolic Blood Pressure units	MMHG

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:55:23

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	12:12 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 12:12
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG

US3032172

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:55:23

Generated On: 11 Aug 2021 21:50:29

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

9 FEB 2021

---

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

---

US3032172

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:55:23

Generated On: 11 Aug 2021 21:50:29

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) 9 FEB 2021

What was the treatment time? (00:00-23:59) 11:39 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 11:39

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

US3032172

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:55:23

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:35:52

Generated On: 11 Aug 2021 21:50:29

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 FEB 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3032172

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:35:52

Generated On: 11 Aug 2021 21:50:29

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3032172

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

---

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	10:09 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 10:09
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	73 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032172

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

19 MAR 2021

---

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

---

US3032172

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:36:10

Generated On: 11 Aug 2021 21:50:29

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 MAR 2021

---

Collection time (*00:00-23:59*) 10:25 (24 HR)

---

Collection date and time (derived) 19 MAR 2021 10:25

---

US3032172

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Sep 2020 17:22:02

Generated On: 11 Aug 2021 21:50:29

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:50:29

AEID	USA-US032-2020-MRNA-1273-P30 1000002
Adverse event	COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	1 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)	08 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:50:29

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:50:29

AEID

Adverse event

UPPER RESPIRATORY  
INFECTION

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)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

08 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

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EAB) (1725)

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:50:29

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:50:29

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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:50:29

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 checked="" type="radio"/> Recovered/Resolved <input 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)	_____

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:50:29

AEID \_\_\_\_\_

Adverse event HYPERTENSION SECONDARY TO HYPOGONADISM

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) 3 DEC 2020

Start time (00:00-23:59) \_\_\_\_\_

AE start date and time (derived) \_\_\_\_\_

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

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:50:29

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

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:50:29

AEID

Adverse event

ACID REFLUX

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

16 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

19 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:50:29

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)	_____

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 17:22:03

Generated On: 11 Aug 2021 21:50:29

---

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

Yes

No

---

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

---

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication MELOXICAM

Prophylaxis Yes   
No

Indication MEDICAL HISTORY:  
ARTHRALGIA-BILATERAL  
KNEES, HIPS, AND SHOULDERS

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

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

---

	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 type="radio"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy) UN UNK 2010

---

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

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication KENALOG

Prophylaxis Yes   
No

Indication MEDICAL HISTORY: CHRONIC  
ITCHING BILATERAL HANDS

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify MG/ML

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 EVERY FOUR MONTHS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

---

	Intraocular	<input type="radio"/>
	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)	UN UNK 2009
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

---

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

---

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

---

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

---

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication GABAPENTIN

Prophylaxis Yes   
No

Indication MEDICAL HISTORY: CHRONIC  
ITCHING BILATERAL HANDS

Dose per administration 300

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 (3)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

---

	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 type="radio"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy) UN UNK 2009

---

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

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Mar 2021 21:13:55

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Name of Medication TESTOSTERONE COMPOUND  
CREAM

Prophylaxis Yes   
No

Indication MEDICAL HISTORY: LOW  
TESTOSTERONE

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 (4)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

---

	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 type="radio"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy)	UN UNK 2014
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"/>

---

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication LORATIDE

Prophylaxis Yes   
No

Indication MEDICAL HISTORY: SEASONAL ALLERGIES

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Mar 2021 21:13:55

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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="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>

---

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication DAYQUIL  
(ACETAMINOPHEN/DEXTROME  
THORPHAN/PHENYLEPHRINE)

Prophylaxis Yes   
No

Indication ADVERSE EVENT: SARS-COV-2  
INFECTION

Dose per administration 325/10/5

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Mar 2021 21:13:55

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- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 02 SEP 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 15 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

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication NYQUIL  
(ACETAMINOPHEN/DEXTROME  
THORPHAN/DOXYLAMINE)

Prophylaxis Yes   
No

Indication ADVERSE EVENT: SARS-COV-2  
INFECTION

Dose per administration 650/30/12.5

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 02 SEP 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 15 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

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication ACETAMINOPHEN

Prophylaxis Yes   
No

Indication ADVERSE EVENT: SARS-COV-2 INFECTION

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

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

---

	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) 02 SEP 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) 15 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

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication SEASONAL INFLUENZA  
VACCINE

Prophylaxis Yes   
No

Indication PROPHYLAXIS FOR SEASONAL  
INFLUENZA

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

---

	Intraocular	<input type="radio"/>
	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) 9 OCT 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) 9 OCT 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

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication TESTOPEL

Prophylaxis Yes   
No

Indication HYPOGONADISM

Dose per administration 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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

---

	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 NOV 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

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

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication LISINOPRIL

Prophylaxis Yes   
No

Indication HYPERTENSION SECONDARY TO HYPOGONADISM

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

---

	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) 3 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) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

Name of Medication OMEPRAZOLE

Prophylaxis Yes   
No

Indication ACID REFLUX

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

430 of 2637

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Mar 2021 21:13:55

Generated On: 11 Aug 2021 21:50:29

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 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3032172

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Sep 2020 17:22:03

Generated On: 11 Aug 2021 21:50:29

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3032172

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 08 Nov 2020 23:37:17

Generated On: 11 Aug 2021 21:50:29

---

Date of dosing discontinuation (dd MMM yyyy) 8 SEP 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 \_\_\_\_\_

---

US3032172

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:50:29

---

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

---

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 05 Oct 2020 16:15:05

Generated On: 11 Aug 2021 21:50:29

SAEID	USA-US032-2020-MRNA-1273-P30 1000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Oct 2020 16:15:05

Generated On: 11 Aug 2021 21:50:29

SAEID	USA-US032-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/SEP/2020 14:36
<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

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Oct 2020 16:15:05

Generated On: 11 Aug 2021 21:50:29

SAEID	USA-US032-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/SEP/2020 10:26
<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

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Oct 2020 16:15:05

Generated On: 11 Aug 2021 21:50:29

SAEID	USA-US032-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/OCT/2020 14:04
<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

US3032172 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

**US3032172**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 21:50:29**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:48:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'US3032172'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:19:22

US3032172

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:01:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:52:20

US3032172

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:01:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:19:23

US3032172

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:01:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:52:20

US3032172

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'SCRN'	System	11 Aug 2020 14:52:20

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered (b) (6) 1963'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:19:24

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '57'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'YEARS'	System	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '57'	System	10 Aug 2020 19:28:29

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Male (M)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '1'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:48

US3032172

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '10 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:29

US3032172

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'Aug 2020'	System	10 Aug 2020 19:28:29

US3032172

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '2020'	System	10 Aug 2020 19:28:29

US3032172

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Amendment 2 (2)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:29

US3032172

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:29

US3032172

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:29

US3032172

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:29

US3032172

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:29

US3032172

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:19:23

US3032172

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '1'	System	10 Aug 2020 19:28:34

US3032172

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:34

US3032172

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:50:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:27
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:08:28

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:29:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:52:29
User closed query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 06 and MH# 07). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 06:29:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Aching in knees - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 23:26:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 23:26:42
Data point term sent to Coder	System	07 Oct 2020 18:34:25
Query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 06 and MH# 07). ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	07 Oct 2020 18:34:11
Coding entries removed.	Samantha Wieseler (b) (4) (b) (4)	07 Oct 2020 18:34:05
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	07 Oct 2020 18:34:05
User entered 'ARTHRALGIA- BILATERAL KNEES' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	07 Oct 2020 18:34:05
User opened query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 06 and MH# 07). ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 17:18:59
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:39
User closed query 'Per DM CLR: Please review and reflect the specific body location of ARTHRALGIA. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 04:20:16

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia multiple - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:44:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:44:38
Data point term sent to Coder	System	17 Sep 2020 21:23:27
Query 'Per DM CLR: Please review and reflect the specific body location of ARTHRALGIA. Update Med History eCRF as appropriate.	Samantha Wieseler (b) (4) (b) (4)	17 Sep 2020 21:23:16
' answered with 'updated' (Site from DM). Coding entries removed.	Samantha Wieseler (b) (4) (b) (4)	17 Sep 2020 21:23:09
User entered 'ARTHRALGIA- bilateral knees, hips, and shoulders' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	17 Sep 2020 21:23:09
User opened query 'Per DM CLR: Please review and reflect the specific body location of ARTHRALGIA. Update Med History eCRF as appropriate.	(b) (4), (b) (6)	30 Aug 2020 08:43:07
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:10:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:10:09
Data point term sent to Coder	System	11 Aug 2020 15:09:28
User entered 'arthralgia'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:08:51

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:29:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'un UNK 2010'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:08:51

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:29:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:08:51

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:29:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:08:51

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:29:26
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:49:49
Signature has been broken.	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	19 Jan 2021 22:42:03
User signature succeeded.	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
Signature has been broken.	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	17 Dec 2020 16:56:53
User signature succeeded.	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	11 Aug 2020 15:08:51
	(b) (4)	

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:29:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:08:51

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'Jan 2010'	System	11 Aug 2020 15:08:51

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '2010'	System	11 Aug 2020 15:08:51

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered empty.	System	11 Aug 2020 15:08:51

US3032172

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered empty.	System	11 Aug 2020 15:08:51

US3032172

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:29:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'Per DM CLR: Please review and reflect the specific body location of ITCHING. Update Med History eCRF as appropriate. '(Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 04:20:35
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus, LLT: Itching both hands - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 23:29:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 23:29:43
Data point term sent to Coder	System	17 Sep 2020 21:24:27
Query 'Per DM CLR: Please review and reflect the specific body location of ITCHING. Update Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	17 Sep 2020 21:23:38
Coding entries removed.	Samantha Wieseler (b) (4)	17 Sep 2020 21:23:33
User entered 'CHRONIC ITCHING- bilateral hands' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	17 Sep 2020 21:23:33
User opened query 'Per DM CLR: Please review and reflect the specific body location of ITCHING. Update Med History eCRF as appropriate. '(Site from DM).	(b) (4), (b) (6)	30 Aug 2020 08:43:53
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus, LLT: Itching - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:20:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:20:17
Data point term sent to Coder	System	11 Aug 2020 15:09:28
User entered 'chronic itching'	Kelsey Kelley (b) (4)	11 Aug 2020 15:09:02

US3032172

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'un UNK 2009'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:02

US3032172

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4)	02 Apr 2021 18:29:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:02

US3032172

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:02

US3032172

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:02

US3032172

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:02

US3032172

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'Jan 2009'	System	11 Aug 2020 15:09:02

US3032172

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '2009'	System	11 Aug 2020 15:09:02

US3032172

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered empty.	System	11 Aug 2020 15:09:02

US3032172

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered empty.	System	11 Aug 2020 15:09:02

US3032172

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User coded data point as SOC: Investigations, HLG: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 15:10:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 15:10:07
Data point term sent to Coder	System	11 Aug 2020 15:09:30
User entered 'Low testosterone'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:20

US3032172

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'un UNK 2014'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:20

US3032172

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4)	02 Apr 2021 18:29:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:20

US3032172

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:20

US3032172

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:20

US3032172

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:20

US3032172

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'Jan 2014'	System	11 Aug 2020 15:09:20

US3032172

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '2014'	System	11 Aug 2020 15:09:20

US3032172

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered empty.	System	11 Aug 2020 15:09:20

US3032172

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered empty.	System	11 Aug 2020 15:09:20

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:07
Query 'Per DM CLR: Please specify the location/laterality (left side or right side) of BENIGN BRONCHIAL CLEFT CYST. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).		06 Nov 2020 05:20:18
User opened query 'Per DM CLR: Please specify the location/laterality (left side or right side) of BENIGN BRONCHIAL CLEFT CYST. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'Per DM CLR: Please review and reflect if the CYST is benign or malignant. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 04:20:47
User coded data point as SOC: Congenital, familial and genetic disorders, HLG: Respiratory disorders congenital, HLT: Pulmonary and bronchial disorders congenital, PT: Bronchogenic cyst, LLT: Bronchial cyst - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 11:44:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 11:44:46
Data point term sent to Coder	System	17 Sep 2020 21:24:27
Query 'Per DM CLR: Please review and reflect if the CYST is benign or malignant. Update Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	17 Sep 2020 21:23:59
Coding entries removed.	Samantha Wieseler (b) (4)	17 Sep 2020 21:23:54
User entered 'Benign BRONCHIAL CLEFT CYST' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	17 Sep 2020 21:23:54

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and reflect if the CYST is benign or malignant. Update Med History eCRF as appropriate.  ' (Site from DM).	(b) (4), (b) (6)	30 Aug 2020 08:43:42
User coded data point as SOC: Congenital, familial and genetic disorders, HLGTT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of face, neck and jaw congenital, PT: Branchial cyst, LLT: Branchial cleft cyst - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 12:32:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 12:32:32
Data point term sent to Coder	System	11 Aug 2020 15:10:31
User entered 'bronchial cleft cyst'	Kelsey Kelley (b) (4)	11 Aug 2020 15:09:34

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:34

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:11
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:34

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User closed query 'Per the source this condition is no longer on going and has stopped un/unk/2018' (Site from CRA).	(b) (4)	13 Apr 2021 16:56:18
DataPoint Verified.	(b) (4)	13 Apr 2021 16:56:05
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:06:48
Query 'Per the source this condition is no longer on going and has stopped un/unk/2018' answered with 'data updated. thank you' (Site from CRA).	(b) (4)	
Signature has been broken.	Chelsie Nutsch (b) (4)	06 Apr 2021 20:57:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per the source this condition is no longer on going and has stopped un/unk/2018' (Site from CRA).	Chelsie Nutsch (b) (4)	06 Apr 2021 20:57:16
User signature succeeded.	(b) (4)	
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	06 Apr 2021 20:57:16
	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 18:29:03
	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
	(b) (4)	
	Kelsey Kelley (b) (4)	11 Aug 2020 15:09:34
	(b) (4)	

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4)	13 Apr 2021 16:56:31
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:06:48
DataPoint Un-verified.	(b) (4)	
	Chelsie Nutsch (b) (4)	06 Apr 2021 20:57:16
Signature has been broken.	(b) (4)	
	Chelsie Nutsch (b) (4)	06 Apr 2021 20:57:16
User entered 'un UNK 2018' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Chelsie Nutsch (b) (4)	06 Apr 2021 20:57:16
	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 18:29:13
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	11 Aug 2020 15:09:34
	(b) (4)	

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:34

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'Jan 2018'	System	11 Aug 2020 15:09:34

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '2018'	System	11 Aug 2020 15:09:34

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'Jan 2018'	System	06 Apr 2021 20:57:16
User entered empty.	System	11 Aug 2020 15:09:34

US3032172

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '2018'	System	06 Apr 2021 20:57:16
User entered empty.	System	11 Aug 2020 15:09:34

US3032172

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	11 Aug 2020 15:11:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 15:11:11
Data point term sent to Coder	System	11 Aug 2020 15:10:31
User entered 'Seasonal allergies'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:45

US3032172

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4)	02 Apr 2021 18:29:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'un UNK 2010'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:45

US3032172

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:45

US3032172

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:45

US3032172

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:45

US3032172

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:29:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:09:45

US3032172

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'Jan 2010'	System	11 Aug 2020 15:09:45

US3032172

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '2010'	System	11 Aug 2020 15:09:45

US3032172

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered empty.	System	11 Aug 2020 15:09:45

US3032172

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered empty.	System	11 Aug 2020 15:09:45

US3032172

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:06:48
User coded data point as SOC: Surgical and medical procedures, HLG: Respiratory tract therapeutic procedures, HLT: Bronchial and pulmonary therapeutic procedures, PT: Lung cyst removal, LLT: Lung cyst removal - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 21:50:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 21:50:31
Data point term sent to Coder	System	06 Apr 2021 21:20:37
User entered 'bronchial left cyst removal'	Kelsey Kelley (b) (4)	06 Apr 2021 21:20:35
DataPoint activated with code reason code Data required.	Kelsey Kelley (b) (4)	06 Apr 2021 21:19:59
DataPoint inactivated with code reason code Data not required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:42:03
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:41:36
DataPoint inactivated with code reason code Data not required.	Kelsey Kelley (b) (4)	17 Dec 2020 16:56:53

US3032172

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:06:48
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 21:20:35
DataPoint activated with code reason code Data required.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 21:19:59
DataPoint inactivated with code reason code Data not required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:42:03
DataPoint activated with code reason code Data required.	(b) (4) Samantha Wieseler (b) (4)	19 Jan 2021 22:41:36
DataPoint inactivated with code reason code Data not required.	Kelsey Kelley (b) (4)	17 Dec 2020 16:56:53

US3032172

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:06:48
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 21:20:35
DataPoint activated with code reason code Data required.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 21:19:59
DataPoint inactivated with code reason code Data not required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:42:03
DataPoint activated with code reason code Data required.	(b) (4) Samantha Wieseler (b) (4)	19 Jan 2021 22:41:36
DataPoint inactivated with code reason code Data not required.	Kelsey Kelley (b) (4)	17 Dec 2020 16:56:53

US3032172

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:06:48
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 21:20:35
DataPoint activated with code reason code Data required.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 21:19:59
DataPoint inactivated with code reason code Data not required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:42:03
DataPoint activated with code reason code Data required.	(b) (4) Samantha Wieseler (b) (4)	19 Jan 2021 22:41:36
DataPoint inactivated with code reason code Data not required.	Kelsey Kelley (b) (4)	17 Dec 2020 16:56:53

US3032172

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:06:48
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 21:20:35
DataPoint activated with code reason code Data required.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 21:19:59
DataPoint inactivated with code reason code Data not required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:42:03
DataPoint activated with code reason code Data required.	(b) (4) Samantha Wieseler (b) (4)	19 Jan 2021 22:41:36
DataPoint inactivated with code reason code Data not required.	Kelsey Kelley (b) (4)	17 Dec 2020 16:56:53

US3032172

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:06:48
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 21:20:35
DataPoint activated with code reason code Data required.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 21:19:59
DataPoint inactivated with code reason code Data not required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:42:03
DataPoint activated with code reason code Data required.	(b) (4) Samantha Wieseler (b) (4)	19 Jan 2021 22:41:36
DataPoint inactivated with code reason code Data not required.	Kelsey Kelley (b) (4)	17 Dec 2020 16:56:53

US3032172

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'Jan 2018'	System	06 Apr 2021 21:20:35
DataPoint activated with code reason code Data required.	Kelsey Kelley (b) (4)	06 Apr 2021 21:19:59
DataPoint inactivated with code reason code Data not required.	(b) (4)	19 Jan 2021 22:42:03
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:41:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	17 Dec 2020 16:56:53

US3032172

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '2018'	System	06 Apr 2021 21:20:35
DataPoint activated with code reason code Data required.	Kelsey Kelley (b) (4)	06 Apr 2021 21:19:59
DataPoint inactivated with code reason code Data not required.	(b) (4)	19 Jan 2021 22:42:03
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:41:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	17 Dec 2020 16:56:53

US3032172

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'Jan 2018'	System	06 Apr 2021 21:20:35
DataPoint activated with code reason code Data required.	Kelsey Kelley (b) (4)	06 Apr 2021 21:19:59
DataPoint inactivated with code reason code Data not required.	(b) (4)	19 Jan 2021 22:42:03
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:41:36
DataPoint inactivated with code reason code Data not required.	Kelsey Kelley (b) (4)	17 Dec 2020 16:56:53

US3032172

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '2018'	System	06 Apr 2021 21:20:35
DataPoint activated with code reason code Data required.	Kelsey Kelley (b) (4)	06 Apr 2021 21:19:59
DataPoint inactivated with code reason code Data not required.	(b) (4)	19 Jan 2021 22:42:03
DataPoint activated with code reason code Data required.	Samantha Wieseler (b) (4)	19 Jan 2021 22:41:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	17 Dec 2020 16:56:53

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '10 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '13:08'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered '10 Aug 2020 13:08'	System	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '177.8' cm	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:02:35
DataPoint set to visible.	(b) (4) System	10 Aug 2020 19:28:34

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '96.6' kg	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:02:35
DataPoint set to visible.	(b) (4) System	10 Aug 2020 19:28:34

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
Amendment Manager: User entered '30.55720'	System	16 Sep 2020 23:50:19
User entered '30.6'	System	11 Aug 2020 15:02:35
DataPoint set to visible.	System	10 Aug 2020 19:28:34

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'kg/m2'	System	11 Aug 2020 15:02:35
DataPoint set to visible.	System	10 Aug 2020 19:28:34

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User closed query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for TEMPERATURE Please update appropriately to "Not done "and not to empty and also remove the units . Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:05:48
Query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for TEMPERATURE Please update appropriately to "Not done "and not to empty and also remove the units . Thanks' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:39:11
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:39:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:39:05
User opened query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for TEMPERATURE Please update appropriately to "Not done "and not to empty and also remove the units . Thanks' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:08:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:39
User entered '37.2' C	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 14:39:05
User entered empty; reason for change Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 14:39:05
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User closed query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update appropriately to "Not done "and not to empty. Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:05:50
Query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update appropriately to "Not done "and not to empty. Thanks' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:39:16
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:39:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 14:39:05
User opened query 'Per CDM: Please note if screening and visit date is same per CCGs pages 15-16, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update appropriately to "Not done "and not to empty. Thanks' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:08:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:39
User entered '72'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'bpm'	System	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 14:39:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 14:39:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:02:35
	(b) (4)	

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'breaths/min'	System	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (.xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 14:39:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 14:39:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '146'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'mmHg'	System	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 14:39:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 14:39:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '92'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:02:35
	(b) (4)	

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User entered 'mmHg'	System	11 Aug 2020 15:02:35

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36

US3032172

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36

US3032172

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:11
User closed query 'Per CDM: Please note that Was the physical examination performed? is recorded as "Yes" at Visit 1 Day 1. Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be completed at Screening and recorded as "No" at Visit 1 Day 1. Please update accordingly, else clarify. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Keith Vrbicky (b) (4)	11 Nov 2020 04:05:09 10 Nov 2020 21:36:59
Query 'Per CDM: Please note that Was the physical examination performed? is recorded as "Yes" at Visit 1 Day 1. Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be completed at Screening and recorded as "No" at Visit 1 Day 1. Please update accordingly, else clarify. ' answered with 'data updated' (Site from DM). Signature has been broken.	Linden DeBoer (b) (4) Linden DeBoer (b) (4)	10 Nov 2020 14:59:27 10 Nov 2020 14:59:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	10 Nov 2020 14:59:08
User opened query 'Per CDM: Please note that Was the physical examination performed? is recorded as "Yes" at Visit 1 Day 1. Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be completed at Screening and recorded as "No" at Visit 1 Day 1. Please update accordingly, else clarify. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Keith Vrbicky (b) (4)	06 Nov 2020 16:56:02 28 Sep 2020 17:22:39
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	15 Sep 2020 21:04:27
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	11 Aug 2020 15:02:42

US3032172

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:36:59
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	10 Nov 2020 14:59:08
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	10 Nov 2020 14:59:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	15 Sep 2020 21:04:27
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	15 Sep 2020 21:04:27
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	15 Sep 2020 19:34:10
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	11 Aug 2020 15:02:58
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	11 Aug 2020 15:02:58
User entered '10 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Aug 2020 15:02:58
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4) System	11 Aug 2020 15:02:42
User entered '11 Aug 2020'	Kelsey Kelley (b) (4)	11 Aug 2020 15:02:42

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Border Protection and Military Personnel](#) (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4)	02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4)	02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '1'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:54:16
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.	(b) (4)	02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:54:16
	(b) (4)	

US3032172

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:36
DataPoint Verified.		02 Apr 2021 18:30:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:54:16

US3032172

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:39:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:06

US3032172

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:39:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '10 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:06

US3032172

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:39:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:06

US3032172

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'VISIT1'	System	11 Aug 2020 14:53:06

US3032172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:39:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:59:16

US3032172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4)	03 Dec 2020 15:39:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:21:31
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:21:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 18:59:16
User entered '102685' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:59:16

US3032172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:39:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:59:16

US3032172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:39:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:16

US3032172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:39:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:16

US3032172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:39:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:16

US3032172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:39:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:16

US3032172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:39:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:53:16

US3032172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:28
User signature succeeded.	Keith Vrbicky (b) (4)	02 Nov 2020 22:05:33
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 07:03:42
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'done' (Site from DM).	Kelsey Kelley (b) (4)	29 Oct 2020 16:58:01
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	29 Oct 2020 16:57:53
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 22:36:06
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:16:46
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:17:32

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:52:29
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 04:50:02
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:18:52
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:18:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:18:13
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:34:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:39
User entered '177.8' cm	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:52:29
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	12 Oct 2020 12:18:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	12 Oct 2020 12:18:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '96.6' kg	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:52:29
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 04:50:02
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:18:52
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:18:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:18:13
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:34:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:39
User entered '177.8' cm	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:52:29
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	12 Oct 2020 12:18:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	12 Oct 2020 12:18:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '96.6' kg	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:39
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Aug 2020 15:04:13
User entered '10 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:04:13
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Aug 2020 15:03:47
User entered '11 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	11 Aug 2020 15:04:13
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	11 Aug 2020 15:03:47
User entered '13:08'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '10 Aug 2020 13:08'	System	11 Aug 2020 15:04:13
User entered '11 Aug 2020 13:08'	System	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '37.2' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '72'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'bpm'	System	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'breaths/min'	System	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '140' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	11 Aug 2020 15:04:13
User entered '146'	(b) (4)	
	Kelsey Kelley (b) (4)	11 Aug 2020 15:03:47
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'mmHg'	System	11 Aug 2020 15:03:47

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:30:49
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:51
DataPoint Un-verified.	(b) (4) Samantha Wieseler (b) (4)	08 Dec 2020 19:45:59
Signature has been broken.	(b) (4) Samantha Wieseler (b) (4)	08 Dec 2020 19:45:59
User entered '89' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	08 Dec 2020 19:45:59
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '92'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'mmHg'	System	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:52:29
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 04:50:02
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:18:52
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:18:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	12 Oct 2020 12:18:13
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:34:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:39
User entered '177.8' cm	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:52:29
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	12 Oct 2020 12:18:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	12 Oct 2020 12:18:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '96.6' kg	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:03:47

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:06:14

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:06:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '10 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:06:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 08:29:46
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 min per protocol' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:08:16
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 15:08:05
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 15:08:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Aug 2020 15:08:05
User entered '14:58' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:08:05
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 15:06:14
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:06:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '10 Aug 2020 14:58'	System	11 Aug 2020 15:08:05
User entered empty.	System	11 Aug 2020 15:06:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 15:08:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 15:08:05
User entered '36.8' C reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Aug 2020 15:08:05
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 15:06:14
User entered empty.	System	11 Aug 2020 15:06:14
	Kelsey Kelley (b) (4)	11 Aug 2020 15:06:14
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:39
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 15:08:05
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:08:05
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 15:06:14
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:06:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 15:06:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 15:08:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 15:08:05
User entered '60' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Aug 2020 15:08:05
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 15:06:14
User entered empty.	Kelsey Kelley (b) (4)	11 Aug 2020 15:06:14

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'bpm'	System	11 Aug 2020 15:08:05
User entered empty.	System	11 Aug 2020 15:06:14

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 15:08:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 15:08:05
User entered '16' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Aug 2020 15:08:05
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 15:06:14
User entered empty.	Kelsey Kelley (b) (4)	11 Aug 2020 15:06:14

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'breaths/min'	System	11 Aug 2020 15:08:05
User entered empty.	System	11 Aug 2020 15:06:14

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 15:08:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 15:08:05
User entered '130' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Aug 2020 15:08:05
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 15:06:14
User entered empty.	Kelsey Kelley (b) (4)	11 Aug 2020 15:06:14

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'mmHg'	System	11 Aug 2020 15:08:05
User entered empty.	System	11 Aug 2020 15:06:14

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 15:08:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 15:08:05
User entered '76' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Aug 2020 15:08:05
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 15:06:14
User entered empty.	Kelsey Kelley (b) (4)	11 Aug 2020 15:06:14

US3032172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'mmHg'	System	11 Aug 2020 15:08:05
User entered empty.	System	11 Aug 2020 15:06:14

US3032172

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:40:43
User closed query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM).		11 Nov 2020 04:04:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:36:59
Query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' answered with 'data updated' (Site from DM).	(b) (4) Linden DeBoer (b) (4)	10 Nov 2020 14:56:33
Signature has been broken.	Linden DeBoer (b) (4)	10 Nov 2020 14:56:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	10 Nov 2020 14:56:24
User opened query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:25:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:56:07

US3032172

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:40:43
User signature succeeded.	Keith Vrbicky (b) (4)	10 Nov 2020 21:36:59
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	10 Nov 2020 14:56:24
User entered empty; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	10 Nov 2020 14:56:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	11 Aug 2020 14:56:15
User entered '10 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Aug 2020 14:56:15
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	11 Aug 2020 14:56:07
User entered '11 Aug 2020'	Kelsey Kelley (b) (4)	11 Aug 2020 14:56:07

US3032172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:40:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:51

US3032172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:40:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	10 Aug 2020 19:28:51

US3032172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:40:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:51

US3032172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 19:28:51

US3032172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:40:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '10 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:51

US3032172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:40:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '14:26'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:51

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '10 Aug 2020 14:26'	System	10 Aug 2020 19:28:51

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:40:48
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Aug 2020 19:28:51

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:40:48
User entered 'ONCE'	System	10 Aug 2020 19:28:51

US3032172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 19:28:51

US3032172

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:41:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:37

US3032172

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:41:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '10 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:37

US3032172

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:41:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '13:50'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:37

US3032172

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '10 Aug 2020 13:50'	System	11 Aug 2020 15:10:37

US3032172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User closed query 'Per GCL Lab Reconciliation: Re-query: Swab: response noted, However, covid diagnostic test for the swab sample collected on 03Sep2020 is note yet entered. Please confirm if a sample was collected on that day and enter in EDC.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 06:34:13
Query 'Per GCL Lab Reconciliation: Re-query: Swab: response noted, However, covid diagnostic test for the swab sample collected on 03Sep2020 is note yet entered. Please confirm if a sample was collected on that day and enter in EDC.' answered with 'subject had illness visit and swab done 01 Sep' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	23 Dec 2020 19:50:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:41:40
User opened query 'Per GCL Lab Reconciliation: Re-query: Swab: response noted, However, covid diagnostic test for the swab sample collected on 03Sep2020 is note yet entered. Please confirm if a sample was collected on that day and enter in EDC.' (Site from DM).		23 Nov 2020 14:18:12
User closed query 'Per GCL Lab Reconciliation re-query: SWAB: Response noted. However, Covid Diagnostic Test sample collected on 03Sep2020 is not yet entered in EDC.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:15:44
Query 'Per GCL Lab Reconciliation re-query: SWAB: Response noted. However, Covid Diagnostic Test sample collected on 03Sep2020 is not yet entered in EDC.' answered with 'ILLNESS VISIT FORMS ALREADY COMPLETED' (Site from DM).	Russell Herstein (b) (4) (b) (4)	20 Nov 2020 22:07:10
User opened query 'Per GCL Lab Reconciliation re-query: SWAB: Response noted. However, Covid Diagnostic Test sample collected on 03Sep2020 is not yet entered in EDC.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:31:29

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 03SEP2020 is reported under Unscheduled visit in PPD central lab, however sample details are missing in EDC. Please reconcile, if correct then update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:31:29
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 03SEP2020 is reported under Unscheduled visit in PPD central lab, however sample details are missing in EDC. Please reconcile, if correct then update as appropriate. Else clarify, thank you.' answered with 'ALL DATA ENTERED IN EDC' (Site from DM).	Russell Herstein (b) (4) (b) (4)	18 Nov 2020 00:58:58
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 03SEP2020 is reported under Unscheduled visit in PPD central lab, however sample details are missing in EDC. Please reconcile, if correct then update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:32:37
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:39
User entered '10 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:19

US3032172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:19

US3032172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:41:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:19

US3032172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:41:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '13:34'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:19

US3032172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '10 Aug 2020 13:34'	System	11 Aug 2020 15:10:19

US3032172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:19

US3032172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:41:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:19

US3032172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:41:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:19

US3032172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered empty.	System	11 Aug 2020 15:10:19

US3032172

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:41:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 15:10:22

US3032172

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '1'	System	11 Aug 2020 15:10:22

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T14:58:55', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '916026fb-2ffb-43e7-bd33-717a50d73a6b' User entered 'Yes (Y)'	System	10 Aug 2020 19:59:36
	System	10 Aug 2020 19:59:36

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T14:59:03', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '916026fb-2ffb-43e7-bd33-717a50d73a6b' User entered '98.2'	System	10 Aug 2020 19:59:36
	System	10 Aug 2020 19:59:36

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T14:59:27', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '916026fb-2ffb-43e7-bd33-717a50d73a6b'	System	10 Aug 2020 19:59:36
User entered 'No (N)'	System	10 Aug 2020 19:59:36

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T14:59:33', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '916026fb-2ffb-43e7-bd33-717a50d73a6b' User entered '10 Aug 2020 14:59'	System	10 Aug 2020 19:59:36
	System	10 Aug 2020 19:59:36

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '10 Aug 2020 14:46'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '10 Aug 2020 17:16'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:11:45', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '6c1b0cef-f14b-456d-bd49-5b2f46d7f410'	System	10 Aug 2020 23:12:21
User entered 'Yes (Y)'	System	10 Aug 2020 23:12:21

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:08', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '6c1b0cef-f14b-456d-bd49-5b2f46d7f410'	System	10 Aug 2020 23:12:21
User entered '96.8'	System	10 Aug 2020 23:12:21

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:14', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '6c1b0cef-f14b-456d-bd49-5b2f46d7f410'	System	10 Aug 2020 23:12:21
User entered 'No (N)'	System	10 Aug 2020 23:12:21

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:19', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '6c1b0cef-f14b-456d-bd49-5b2f46d7f410'	System	10 Aug 2020 23:12:21
User entered '10 Aug 2020 18:12'	System	10 Aug 2020 23:12:21

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '10 Aug 2020 18:11'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 2'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:03', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'e3aaf315-6282-4c80-ae94-0429c3c4d206'	System	11 Aug 2020 17:30:17
User entered 'Yes (Y)'	System	11 Aug 2020 17:30:17

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:08', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'e3aaf315-6282-4c80-ae94-0429c3c4d206'	System	11 Aug 2020 17:30:17
User entered '97.3'	System	11 Aug 2020 17:30:17

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:11', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'e3aaf315-6282-4c80-ae94-0429c3c4d206'	System	11 Aug 2020 17:30:17
User entered 'No (N)'	System	11 Aug 2020 17:30:17

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:14', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'e3aaf315-6282-4c80-ae94-0429c3c4d206' User entered '11 Aug 2020 12:30'	System	11 Aug 2020 17:30:17
	System	11 Aug 2020 17:30:17

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 3'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:12:21', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3f1c6d2a-b886-4a72-b3f0-a16a57d1ce45'	System	12 Aug 2020 20:12:36
User entered 'Yes (Y)'	System	12 Aug 2020 20:12:36

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:12:26', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3f1c6d2a-b886-4a72-b3f0-a16a57d1ce45' User entered '98.2'	System	12 Aug 2020 20:12:36
	System	12 Aug 2020 20:12:36

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:12:31', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3f1c6d2a-b886-4a72-b3f0-a16a57d1ce45'	System	12 Aug 2020 20:12:36
User entered 'No (N)'	System	12 Aug 2020 20:12:36

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:12:35', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3f1c6d2a-b886-4a72-b3f0-a16a57d1ce45' User entered '12 Aug 2020 15:12'	System	12 Aug 2020 20:12:36
	System	12 Aug 2020 20:12:36

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 4'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:26:02', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8cb6983b-acf0-4352-9e34-d79c92628ec4' User entered 'Yes (Y)'	System	13 Aug 2020 17:26:42
	System	13 Aug 2020 17:26:42

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:26:31', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8cb6983b-acf0-4352-9e34-d79c92628ec4' User entered '97.9'	System	13 Aug 2020 17:26:42
	System	13 Aug 2020 17:26:42

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:26:35', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8cb6983b-acf0-4352-9e34-d79c92628ec4' User entered 'No (N)'	System	13 Aug 2020 17:26:42
	System	13 Aug 2020 17:26:42

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:26:38', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8cb6983b-acf0-4352-9e34-d79c92628ec4' User entered '13 Aug 2020 12:26'	System	13 Aug 2020 17:26:42
	System	13 Aug 2020 17:26:42

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 5'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:01:36', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '4348e50d-2fb2-4eee-91c3-72c776e3d6e0' User entered 'Yes (Y)'	System	14 Aug 2020 19:01:51
	System	14 Aug 2020 19:01:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:01:43', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '4348e50d-2fb2-4eee-91c3-72c776e3d6e0' User entered '96.9'	System	14 Aug 2020 19:01:51
	System	14 Aug 2020 19:01:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:01:46', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '4348e50d-2fb2-4eee-91c3-72c776e3d6e0' User entered 'No (N)'	System	14 Aug 2020 19:01:51
	System	14 Aug 2020 19:01:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:01:49', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '4348e50d-2fb2-4eee-91c3-72c776e3d6e0' User entered '14 Aug 2020 14:01'	System	14 Aug 2020 19:01:51
	System	14 Aug 2020 19:01:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 6'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:00:30', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'af3991b3-bf71-430c-b93f-7b651f32ca84' User entered 'Yes (Y)'	System	15 Aug 2020 17:01:08
	System	15 Aug 2020 17:01:08

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:00:54', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'af3991b3-bf71-430c-b93f-7b651f32ca84' User entered '97.3'	System	15 Aug 2020 17:01:08
	System	15 Aug 2020 17:01:08

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:00:58', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'af3991b3-bf71-430c-b93f-7b651f32ca84'	System	15 Aug 2020 17:01:08
User entered 'No (N)'	System	15 Aug 2020 17:01:08

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:01', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'af3991b3-bf71-430c-b93f-7b651f32ca84' User entered '15 Aug 2020 12:01'	System	15 Aug 2020 17:01:08
	System	15 Aug 2020 17:01:08

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 7'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:00:29', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'edee54a1-3a67-4f05-83b4-d739b7de8368' User entered 'Yes (Y)'	System	16 Aug 2020 17:01:10
	System	16 Aug 2020 17:01:10

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:00:57', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'edee54a1-3a67-4f05-83b4-d739b7de8368' User entered '98.5'	System	16 Aug 2020 17:01:10
	System	16 Aug 2020 17:01:10

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:00:59', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'edee54a1-3a67-4f05-83b4-d739b7de8368' User entered 'No (N)'	System	16 Aug 2020 17:01:10
	System	16 Aug 2020 17:01:10

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:03', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'edee54a1-3a67-4f05-83b4-d739b7de8368' User entered '16 Aug 2020 12:01'	System	16 Aug 2020 17:01:10
	System	16 Aug 2020 17:01:10

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T14:59:44', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '95d8f7de-0ae5-46be-80db-ba12ed9c18e2'	System	10 Aug 2020 20:00:12
User entered 'None (1)'	System	10 Aug 2020 20:00:12

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T14:59:47', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '95d8f7de-0ae5-46be-80db-ba12ed9c18e2' User entered 'No (N)'	System	10 Aug 2020 20:00:12
	System	10 Aug 2020 20:00:12

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T14:59:50', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '95d8f7de-0ae5-46be-80db-ba12ed9c18e2'	System	10 Aug 2020 20:00:12
User entered 'No (N)'	System	10 Aug 2020 20:00:12

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T15:00:07', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '95d8f7de-0ae5-46be-80db-ba12ed9c18e2'	System	10 Aug 2020 20:00:12
User entered 'None (1)'	System	10 Aug 2020 20:00:12

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T15:00:10', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '95d8f7de-0ae5-46be-80db-ba12ed9c18e2' User entered '10 Aug 2020 15:00'	System	10 Aug 2020 20:00:12
	System	10 Aug 2020 20:00:12

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '10 Aug 2020 14:46'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '10 Aug 2020 17:16'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:13:03', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '618ff155-a281-4180-8d48-d0a2ae8a3f57'	System	10 Aug 2020 23:13:26
User entered 'None (1)'	System	10 Aug 2020 23:13:26

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:13:14', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '618ff155-a281-4180-8d48-d0a2ae8a3f57'	System	10 Aug 2020 23:13:26
User entered 'No (N)'	System	10 Aug 2020 23:13:26

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:13:18', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '618ff155-a281-4180-8d48-d0a2ae8a3f57'	System	10 Aug 2020 23:13:26
User entered 'No (N)'	System	10 Aug 2020 23:13:26

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:13:21', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '618ff155-a281-4180-8d48-d0a2ae8a3f57'	System	10 Aug 2020 23:13:26
User entered 'None (1)'	System	10 Aug 2020 23:13:26

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:13:24', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '618ff155-a281-4180-8d48-d0a2ae8a3f57'	System	10 Aug 2020 23:13:26
User entered '10 Aug 2020 18:13'	System	10 Aug 2020 23:13:26

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '10 Aug 2020 18:11'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 2'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:20', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '88e013eb-e269-42ee-a338-de2f43b6a187'	System	11 Aug 2020 17:30:40
User entered 'None (1)'	System	11 Aug 2020 17:30:40

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:23', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '88e013eb-e269-42ee-a338-de2f43b6a187'	System	11 Aug 2020 17:30:40
User entered 'No (N)'	System	11 Aug 2020 17:30:40

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:28', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '88e013eb-e269-42ee-a338-de2f43b6a187'	System	11 Aug 2020 17:30:40
User entered 'No (N)'	System	11 Aug 2020 17:30:40

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:33', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '88e013eb-e269-42ee-a338-de2f43b6a187'	System	11 Aug 2020 17:30:40
User entered 'None (1)'	System	11 Aug 2020 17:30:40

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:36', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '88e013eb-e269-42ee-a338-de2f43b6a187' User entered '11 Aug 2020 12:30'	System	11 Aug 2020 17:30:40
	System	11 Aug 2020 17:30:40

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 3'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:12:41', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '7ba63b64-c901-4062-b9f7-4d2369767d43'	System	12 Aug 2020 20:13:00
User entered 'None (1)'	System	12 Aug 2020 20:13:00

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:12:44', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '7ba63b64-c901-4062-b9f7-4d2369767d43'	System	12 Aug 2020 20:13:00
User entered 'No (N)'	System	12 Aug 2020 20:13:00

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:12:47', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '7ba63b64-c901-4062-b9f7-4d2369767d43'	System	12 Aug 2020 20:13:00
User entered 'No (N)'	System	12 Aug 2020 20:13:00

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:12:54', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '7ba63b64-c901-4062-b9f7-4d2369767d43'	System	12 Aug 2020 20:13:00
User entered 'None (1)'	System	12 Aug 2020 20:13:00

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:12:58', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '7ba63b64-c901-4062-b9f7-4d2369767d43' User entered '12 Aug 2020 15:12'	System	12 Aug 2020 20:13:00
	System	12 Aug 2020 20:13:00

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 4'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:26:46', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8ca50978-1b17-4cee-b9ec-630f47a914b6'	System	13 Aug 2020 17:27:02
User entered 'None (1)'	System	13 Aug 2020 17:27:02

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:26:50', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8ca50978-1b17-4cee-b9ec-630f47a914b6'	System	13 Aug 2020 17:27:02
User entered 'No (N)'	System	13 Aug 2020 17:27:02

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:26:52', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8ca50978-1b17-4cee-b9ec-630f47a914b6'	System	13 Aug 2020 17:27:02
User entered 'No (N)'	System	13 Aug 2020 17:27:02

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:26:55', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8ca50978-1b17-4cee-b9ec-630f47a914b6'	System	13 Aug 2020 17:27:02
User entered 'None (1)'	System	13 Aug 2020 17:27:02

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:26:57', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8ca50978-1b17-4cee-b9ec-630f47a914b6' User entered '13 Aug 2020 12:26'	System	13 Aug 2020 17:27:02
	System	13 Aug 2020 17:27:02

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 5'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:01:52', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '37e2639c-9453-4f1e-965b-2b5456bc06e3' User entered 'None (1)'	System	14 Aug 2020 19:02:09
	System	14 Aug 2020 19:02:09

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:01:55', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '37e2639c-9453-4f1e-965b-2b5456bc06e3' User entered 'No (N)'	System	14 Aug 2020 19:02:09
	System	14 Aug 2020 19:02:09

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:01', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '37e2639c-9453-4f1e-965b-2b5456bc06e3' User entered 'No (N)'	System	14 Aug 2020 19:02:09
	System	14 Aug 2020 19:02:09

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:04', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '37e2639c-9453-4f1e-965b-2b5456bc06e3' User entered 'None (1)'	System	14 Aug 2020 19:02:09
	System	14 Aug 2020 19:02:09

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:07', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '37e2639c-9453-4f1e-965b-2b5456bc06e3' User entered '14 Aug 2020 14:02'	System	14 Aug 2020 19:02:09
	System	14 Aug 2020 19:02:09

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 6'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:05', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '827f7576-2eaf-4247-b0e0-af36a2110cbf'	System	15 Aug 2020 17:01:18
User entered 'None (1)'	System	15 Aug 2020 17:01:18

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:07', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '827f7576-2eaf-4247-b0e0-af36a2110cbf' User entered 'No (N)'	System	15 Aug 2020 17:01:18
	System	15 Aug 2020 17:01:18

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:09', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '827f7576-2eaf-4247-b0e0-af36a2110cbf' User entered 'No (N)'	System	15 Aug 2020 17:01:18
	System	15 Aug 2020 17:01:18

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:13', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '827f7576-2eaf-4247-b0e0-af36a2110cbf'	System	15 Aug 2020 17:01:18
User entered 'None (1)'	System	15 Aug 2020 17:01:18

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:15', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '827f7576-2eaf-4247-b0e0-af36a2110cbf' User entered '15 Aug 2020 12:01'	System	15 Aug 2020 17:01:18
	System	15 Aug 2020 17:01:18

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 7'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (5)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:12', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'dd49e39b-105d-4c72-b8b8-c399df080815' User entered 'None (1)'	System	16 Aug 2020 17:01:28
	System	16 Aug 2020 17:01:28

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:18', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'dd49e39b-105d-4c72-b8b8-c399df080815' User entered 'No (N)'	System	16 Aug 2020 17:01:28
	System	16 Aug 2020 17:01:28

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:21', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'dd49e39b-105d-4c72-b8b8-c399df080815' User entered 'No (N)'	System	16 Aug 2020 17:01:28
	System	16 Aug 2020 17:01:28

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:24', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'dd49e39b-105d-4c72-b8b8-c399df080815'	System	16 Aug 2020 17:01:28
User entered 'None (1)'	System	16 Aug 2020 17:01:28

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:26', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'dd49e39b-105d-4c72-b8b8-c399df080815' User entered '16 Aug 2020 12:01'	System	16 Aug 2020 17:01:28
	System	16 Aug 2020 17:01:28

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T15:00:18', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ebb2bca2-2b11-43cb-9683-c5ee1f217c30' User entered 'None (0)'	System	10 Aug 2020 20:00:45
	System	10 Aug 2020 20:00:45

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T15:00:22', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ebb2bca2-2b11-43cb-9683-c5ee1f217c30' User entered 'None (0)'	System	10 Aug 2020 20:00:45
	System	10 Aug 2020 20:00:45

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T15:00:25', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ebb2bca2-2b11-43cb-9683-c5ee1f217c30' User entered 'None (0)'	System	10 Aug 2020 20:00:45
	System	10 Aug 2020 20:00:45

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T15:00:28', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ebb2bca2-2b11-43cb-9683-c5ee1f217c30' User entered 'None (0)'	System	10 Aug 2020 20:00:45
	System	10 Aug 2020 20:00:45

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T15:00:33', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ebb2bca2-2b11-43cb-9683-c5ee1f217c30' User entered 'None (0)'	System	10 Aug 2020 20:00:45
	System	10 Aug 2020 20:00:45

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T15:00:36', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ebb2bca2-2b11-43cb-9683-c5ee1f217c30' User entered 'None (0)'	System	10 Aug 2020 20:00:45
	System	10 Aug 2020 20:00:45

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T15:00:38', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ebb2bca2-2b11-43cb-9683-c5ee1f217c30' User entered 'No (N)'	System	10 Aug 2020 20:00:45
	System	10 Aug 2020 20:00:45

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T15:00:42', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ebb2bca2-2b11-43cb-9683-c5ee1f217c30' User entered '10 Aug 2020 15:00'	System	10 Aug 2020 20:00:45
	System	10 Aug 2020 20:00:45

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '10 Aug 2020 14:46'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '10 Aug 2020 17:16'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:25', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '594faf56-bf56-45f8-a001-21300b5816e6' User entered 'None (0)'	System	10 Aug 2020 23:12:59
	System	10 Aug 2020 23:12:59

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:28', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '594faf56-bf56-45f8-a001-21300b5816e6'	System	10 Aug 2020 23:12:59
User entered 'None (0)'	System	10 Aug 2020 23:12:59

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:31', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '594faf56-bf56-45f8-a001-21300b5816e6' User entered 'None (0)'	System	10 Aug 2020 23:12:59
	System	10 Aug 2020 23:12:59

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:34', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '594faf56-bf56-45f8-a001-21300b5816e6' User entered 'None (0)'	System	10 Aug 2020 23:12:59
	System	10 Aug 2020 23:12:59

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:43', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '594faf56-bf56-45f8-a001-21300b5816e6'	System	10 Aug 2020 23:12:59
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Aug 2020 23:12:59

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:46', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '594faf56-bf56-45f8-a001-21300b5816e6' User entered 'None (0)'	System	10 Aug 2020 23:12:59
	System	10 Aug 2020 23:12:59

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:51', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '594faf56-bf56-45f8-a001-21300b5816e6' User entered 'No (N)'	System	10 Aug 2020 23:12:59
	System	10 Aug 2020 23:12:59

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-10T18:12:58', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '594faf56-bf56-45f8-a001-21300b5816e6' User entered '10 Aug 2020 18:12'	System	10 Aug 2020 23:12:59
	System	10 Aug 2020 23:12:59

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '10 Aug 2020 18:11'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 2'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:42', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3b1d62e4-849b-47f6-a660-9bc60f2918ef' User entered 'None (0)'	System	11 Aug 2020 17:31:04
	System	11 Aug 2020 17:31:04

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:47', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3b1d62e4-849b-47f6-a660-9bc60f2918ef' User entered 'None (0)'	System	11 Aug 2020 17:31:04
	System	11 Aug 2020 17:31:04

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:49', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3b1d62e4-849b-47f6-a660-9bc60f2918ef' User entered 'None (0)'	System	11 Aug 2020 17:31:04
	System	11 Aug 2020 17:31:04

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:52', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3b1d62e4-849b-47f6-a660-9bc60f2918ef' User entered 'None (0)'	System	11 Aug 2020 17:31:04
	System	11 Aug 2020 17:31:04

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:54', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3b1d62e4-849b-47f6-a660-9bc60f2918ef' User entered 'None (0)'	System	11 Aug 2020 17:31:04
	System	11 Aug 2020 17:31:04

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:56', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3b1d62e4-849b-47f6-a660-9bc60f2918ef' User entered 'None (0)'	System	11 Aug 2020 17:31:04
	System	11 Aug 2020 17:31:04

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:30:59', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3b1d62e4-849b-47f6-a660-9bc60f2918ef' User entered 'No (N)'	System	11 Aug 2020 17:31:04
	System	11 Aug 2020 17:31:04

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-11T12:31:01', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3b1d62e4-849b-47f6-a660-9bc60f2918ef' User entered '11 Aug 2020 12:31'	System	11 Aug 2020 17:31:04
	System	11 Aug 2020 17:31:04

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 3'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:13:02', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c783b6ab-d5bd-4cf0-b936-5fd7ab10f7f0'	System	12 Aug 2020 20:13:25
User entered 'None (0)'	System	12 Aug 2020 20:13:25

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:13:09', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c783b6ab-d5bd-4cf0-b936-5fd7ab10f7f0' User entered 'None (0)'	System	12 Aug 2020 20:13:25
	System	12 Aug 2020 20:13:25

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:13:12', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c783b6ab-d5bd-4cf0-b936-5fd7ab10f7f0' User entered 'None (0)'	System	12 Aug 2020 20:13:25
	System	12 Aug 2020 20:13:25

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:13:14', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c783b6ab-d5bd-4cf0-b936-5fd7ab10f7f0' User entered 'None (0)'	System	12 Aug 2020 20:13:25
	System	12 Aug 2020 20:13:25

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:13:17', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c783b6ab-d5bd-4cf0-b936-5fd7ab10f7f0' User entered 'None (0)'	System	12 Aug 2020 20:13:25
	System	12 Aug 2020 20:13:25

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:13:18', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c783b6ab-d5bd-4cf0-b936-5fd7ab10f7f0' User entered 'None (0)'	System	12 Aug 2020 20:13:25
	System	12 Aug 2020 20:13:25

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:13:21', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c783b6ab-d5bd-4cf0-b936-5fd7ab10f7f0'	System	12 Aug 2020 20:13:25
User entered 'No (N)'	System	12 Aug 2020 20:13:25

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-12T15:13:23', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c783b6ab-d5bd-4cf0-b936-5fd7ab10f7f0' User entered '12 Aug 2020 15:13'	System	12 Aug 2020 20:13:25
	System	12 Aug 2020 20:13:25

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 4'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:27:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8bc47269-6315-418b-b300-806532be6a3e' User entered 'None (0)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:27:02', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8bc47269-6315-418b-b300-806532be6a3e'	System	13 Aug 2020 17:27:44
User entered 'None (0)'	System	13 Aug 2020 17:27:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:27:04', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8bc47269-6315-418b-b300-806532be6a3e'	System	13 Aug 2020 17:27:44
User entered 'None (0)'	System	13 Aug 2020 17:27:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:27:06', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8bc47269-6315-418b-b300-806532be6a3e' User entered 'None (0)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:27:08', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8bc47269-6315-418b-b300-806532be6a3e' User entered 'None (0)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:27:10', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8bc47269-6315-418b-b300-806532be6a3e' User entered 'None (0)'	System	13 Aug 2020 17:27:44
	System	13 Aug 2020 17:27:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:27:39', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8bc47269-6315-418b-b300-806532be6a3e'	System	13 Aug 2020 17:27:44
User entered 'No (N)'	System	13 Aug 2020 17:27:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-13T12:27:42', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '8bc47269-6315-418b-b300-806532be6a3e'	System	13 Aug 2020 17:27:44
User entered '13 Aug 2020 12:27'	System	13 Aug 2020 17:27:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 5'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:11', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '49d2b527-5248-4f2f-8448-a5c7096e90ac' User entered 'None (0)'	System	14 Aug 2020 19:02:44
	System	14 Aug 2020 19:02:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:14', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '49d2b527-5248-4f2f-8448-a5c7096e90ac'	System	14 Aug 2020 19:02:44
User entered 'No interference with activity (1)'	System	14 Aug 2020 19:02:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:17', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '49d2b527-5248-4f2f-8448-a5c7096e90ac' User entered 'None (0)'	System	14 Aug 2020 19:02:44
	System	14 Aug 2020 19:02:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:20', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '49d2b527-5248-4f2f-8448-a5c7096e90ac' User entered 'None (0)'	System	14 Aug 2020 19:02:44
	System	14 Aug 2020 19:02:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:22', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '49d2b527-5248-4f2f-8448-a5c7096e90ac' User entered 'None (0)'	System	14 Aug 2020 19:02:44
	System	14 Aug 2020 19:02:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:25', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '49d2b527-5248-4f2f-8448-a5c7096e90ac' User entered 'None (0)'	System	14 Aug 2020 19:02:44
	System	14 Aug 2020 19:02:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:28', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '49d2b527-5248-4f2f-8448-a5c7096e90ac' User entered 'No (N)'	System	14 Aug 2020 19:02:44
	System	14 Aug 2020 19:02:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-14T14:02:31', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '49d2b527-5248-4f2f-8448-a5c7096e90ac' User entered '14 Aug 2020 14:02'	System	14 Aug 2020 19:02:44
	System	14 Aug 2020 19:02:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 6'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:19', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '77f84d0a-1c9f-43ed-b021-88ff60da0bbe' User entered 'None (0)'	System	15 Aug 2020 17:01:35
	System	15 Aug 2020 17:01:35

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:21', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '77f84d0a-1c9f-43ed-b021-88ff60da0bbe' User entered 'None (0)'	System	15 Aug 2020 17:01:35
	System	15 Aug 2020 17:01:35

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:23', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '77f84d0a-1c9f-43ed-b021-88ff60da0bbe' User entered 'None (0)'	System	15 Aug 2020 17:01:35
	System	15 Aug 2020 17:01:35

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:24', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '77f84d0a-1c9f-43ed-b021-88ff60da0bbe' User entered 'None (0)'	System	15 Aug 2020 17:01:35
	System	15 Aug 2020 17:01:35

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:26', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '77f84d0a-1c9f-43ed-b021-88ff60da0bbe' User entered 'None (0)'	System	15 Aug 2020 17:01:35
	System	15 Aug 2020 17:01:35

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:28', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '77f84d0a-1c9f-43ed-b021-88ff60da0bbe' User entered 'None (0)'	System	15 Aug 2020 17:01:35
	System	15 Aug 2020 17:01:35

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:29', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '77f84d0a-1c9f-43ed-b021-88ff60da0bbe' User entered 'No (N)'	System	15 Aug 2020 17:01:35
	System	15 Aug 2020 17:01:35

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-15T12:01:31', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '77f84d0a-1c9f-43ed-b021-88ff60da0bbe' User entered '15 Aug 2020 12:01'	System	15 Aug 2020 17:01:35
	System	15 Aug 2020 17:01:35

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 7'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:30', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c4e64173-603c-4da8-bc51-d41d104f12d1' User entered 'None (0)'	System	16 Aug 2020 17:01:44
	System	16 Aug 2020 17:01:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:31', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c4e64173-603c-4da8-bc51-d41d104f12d1' User entered 'None (0)'	System	16 Aug 2020 17:01:44
	System	16 Aug 2020 17:01:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:33', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c4e64173-603c-4da8-bc51-d41d104f12d1' User entered 'None (0)'	System	16 Aug 2020 17:01:44
	System	16 Aug 2020 17:01:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:34', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c4e64173-603c-4da8-bc51-d41d104f12d1' User entered 'None (0)'	System	16 Aug 2020 17:01:44
	System	16 Aug 2020 17:01:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:36', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c4e64173-603c-4da8-bc51-d41d104f12d1' User entered 'None (0)'	System	16 Aug 2020 17:01:44
	System	16 Aug 2020 17:01:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:37', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c4e64173-603c-4da8-bc51-d41d104f12d1' User entered 'None (0)'	System	16 Aug 2020 17:01:44
	System	16 Aug 2020 17:01:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:40', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c4e64173-603c-4da8-bc51-d41d104f12d1' User entered 'No (N)'	System	16 Aug 2020 17:01:44
	System	16 Aug 2020 17:01:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-08-16T12:01:42', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c4e64173-603c-4da8-bc51-d41d104f12d1' User entered '16 Aug 2020 12:01'	System	16 Aug 2020 17:01:44
	System	16 Aug 2020 17:01:44

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 19:28:51

US3032172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4)	03 Dec 2020 15:43:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 13:46:40

US3032172

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:43:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '17 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 13:46:40

US3032172

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:43:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 13:46:40

US3032172

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:43:53
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 13:46:40

US3032172

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:43:56
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Aug 2020 13:46:44

US3032172

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '1'	System	18 Aug 2020 13:46:44

US3032172

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:07

US3032172

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '25 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:07

US3032172

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:07

US3032172

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:49:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:07

US3032172

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:11

US3032172

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '1'	System	21 Sep 2020 20:48:11

US3032172

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:49:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:20

US3032172

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:49:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '1 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:20

US3032172

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4)	03 Dec 2020 15:49:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:20

US3032172

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4)	03 Dec 2020 15:49:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:20

US3032172

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4)	03 Dec 2020 15:50:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:23

US3032172

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '1'	System	21 Sep 2020 20:48:23

US3032172

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.	(b) (4)	03 Dec 2020 15:51:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:33

US3032172

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:51:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 03:19:05
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'data correct as entered' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:43
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	21 Sep 2020 20:48:33
User entered '21 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:33

US3032172

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.	(b) (4)	03 Dec 2020 15:51:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:48:33

US3032172

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered 'VISIT2'	System	21 Sep 2020 20:48:33

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '21 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '12:25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered '21 Sep 2020 12:25'	System	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '37.1' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '63'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered 'bpm'	System	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered 'breaths/min'	System	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '136'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered 'mmHg'	System	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '90'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered 'mmHg'	System	21 Sep 2020 20:49:45

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered empty.	System	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.	(b) (4)	03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.	(b) (4)	03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered empty.	System	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered empty.	System	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered empty.	System	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered empty.	System	21 Sep 2020 20:49:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:08

US3032172

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '21 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:08

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.	(b) (4)	03 Dec 2020 15:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:18

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:18

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:18

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered empty.	System	21 Sep 2020 20:50:18

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:18

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:18

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered empty.	System	21 Sep 2020 20:50:18

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:18

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:32
User entered empty.	System	21 Sep 2020 20:50:18

US3032172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered empty.	System	21 Sep 2020 20:50:18

US3032172

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:44

US3032172

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '21 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:44

US3032172

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '13:08'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:44

US3032172

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered '21 Sep 2020 13:08'	System	21 Sep 2020 20:50:44

US3032172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '21 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered '12:43'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered '21 Sep 2020 12:43'	System	21 Sep 2020 20:50:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.	(b) (4)	03 Dec 2020 15:51:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:51:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:50:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered empty.	System	21 Sep 2020 20:50:53

US3032172

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.	(b) (4)	03 Dec 2020 15:51:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:39
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	21 Sep 2020 20:51:25

US3032172

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered '1'	System	21 Sep 2020 20:51:25

US3032172

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:35:54

US3032172

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '28 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:35:54

US3032172

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:35:54

US3032172

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:35:54

US3032172

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:27
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:35:57

US3032172

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '1'	System	19 Oct 2020 19:35:57

US3032172

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:37
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:36:09

US3032172

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:37
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 05OCT2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).		19 Nov 2020 11:32:42
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 05OCT2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' answered with 'data is correct as entered' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	04 Nov 2020 18:56:14
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 05OCT2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 00:32:18
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Oct 2020 14:49:54
User entered '05 Oct 2020'	Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:36:09

US3032172

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:37
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:36:09

US3032172

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:37
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:36:09

US3032172

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:36:16

US3032172

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '1'	System	19 Oct 2020 19:36:16

US3032172

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:46
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:36:48

US3032172

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:46
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '12 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:36:48

US3032172

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		03 Dec 2020 15:52:46
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:36:48

US3032172

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.	(b) (4)	03 Dec 2020 15:52:46
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:36:48

US3032172

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
DataPoint Verified.		21 Dec 2020 18:55:38
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:36:52

US3032172

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '1'	System	19 Oct 2020 19:36:52

US3032172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 05oct2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 05oct2020 is missing in EDC. Please confirm the 05OCT2020 was also collected under Unscheduled visit then please initiate an Unscheduled visit using ADD EVENT option and record the Unscheduled Immunogenicity sample dated 05OCT2020 present in PPD.' (Site from DM).		21 Jan 2021 09:04:43
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 05oct2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 05oct2020 is missing in EDC. Please confirm the 05OCT2020 was also collected under Unscheduled visit then please initiate an Unscheduled visit using ADD EVENT option and record the Unscheduled Immunogenicity sample dated 05OCT2020 present in PPD.' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4)	20 Jan 2021 22:25:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 05oct2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 05oct2020 is missing in EDC. Please confirm the 05OCT2020 was also collected under Unscheduled visit then please initiate an Unscheduled visit using ADD EVENT option and record the Unscheduled Immunogenicity sample dated 05OCT2020 present in PPD.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 12:51:42

US3032172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Site response noted "visit was 05Oct" . However Sample dated 06oct2020 is reported under "Unscheduled visit" in PPD Central lab Immuno. "Immunogenicity Assessment " page under the folder "Unscheduled 05oct2020" is missing in EDC Please review if the sample has been collected then update the details under appropriate Unscheduled 05oct2020 visit. Please confirm to update the date as "05oct2020 Unscheduled " for PPD Central lab Immuno.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 12:48:12
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Site response noted "visit was 05Oct" . However Sample dated 06oct2020 is reported under "Unscheduled visit" in PPD Central lab Immuno. "Immunogenicity Assessment " page under the folder "Unscheduled 05oct2020" is missing in EDC Please review if the sample has been collected then update the details under appropriate Unscheduled 05oct2020 visit. Please confirm to update the date as "05oct2020 Unscheduled " for PPD Central lab Immuno.' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4)	19 Jan 2021 22:55:05
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:53:45
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 06oct2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:00:25

US3032172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Site response noted "visit was 05Oct" . However Sample dated 06oct2020 is reported under "Unscheduled visit" in PPD Central lab Immuno. "Immunogenicity Assessment " page under the folder "Unscheduled 05oct2020" is missing in EDC Please review if the sample has been collected then update the details under appropriate Unscheduled 05oct2020 visit. Please confirm to update the date as "05oct2020 Unscheduled " for PPD Central lab Immuno.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:00:17
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 06oct2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' answered with 'visit was 05Oct' (Site from DM).	Russell Herstein (b) (4) (b) (4)	18 Nov 2020 21:54:41
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 06oct2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:14:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:37:12

US3032172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:53:48
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:37:12

US3032172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:53:49
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:37:12

US3032172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered 'VISIT3'	System	19 Oct 2020 19:37:12

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.	(b) (4)	03 Dec 2020 15:55:06
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:06
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:06
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '10:17'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered '19 Oct 2020 10:17'	System	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:06
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '37.1' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:06
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:06
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:06
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '84'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered 'bpm'	System	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:06
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered 'breaths/min'	System	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:06
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '139'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered 'mmHg'	System	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:06
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '75'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered 'mmHg'	System	19 Oct 2020 19:38:14

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19

US3032172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19

US3032172

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:18
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:21

US3032172

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:18
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:21

US3032172

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:35

US3032172

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '19 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:35

US3032172

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:41
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered '10:25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:35

US3032172

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered '19 Oct 2020 10:25'	System	19 Oct 2020 19:38:35

US3032172

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
DataPoint Verified.		03 Dec 2020 15:55:46
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 19:38:46

US3032172

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:19
User entered '1'	System	19 Oct 2020 19:38:46

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 64'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-10-12T12:00:43', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '38377563-6dcc-47c8-b36c-8fa2308812d2'	System	12 Oct 2020 17:01:48
User entered 'No (N)'	System	12 Oct 2020 17:01:48

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-10-12T12:00:48', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '38377563-6dcc-47c8-b36c-8fa2308812d2'	System	12 Oct 2020 17:01:48
User entered 'No (N)'	System	12 Oct 2020 17:01:48

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-10-12T12:00:54', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '38377563-6dcc-47c8-b36c-8fa2308812d2' User entered '12 Oct 2020 12:00:54'	System	12 Oct 2020 17:01:48
	System	12 Oct 2020 17:01:48

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 71'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-10-19T12:00:46', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '862fee94-52e0-46da-94cb-e9647070cd01'	System	19 Oct 2020 17:00:59
User entered 'No (N)'	System	19 Oct 2020 17:00:59

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-10-19T12:00:51', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '862fee94-52e0-46da-94cb-e9647070cd01'	System	19 Oct 2020 17:00:59
User entered 'No (N)'	System	19 Oct 2020 17:00:59

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-10-19T12:00:54', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '862fee94-52e0-46da-94cb-e9647070cd01' User entered '19 Oct 2020 12:00:54'	System	19 Oct 2020 17:00:59
	System	19 Oct 2020 17:00:59

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 78'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-10-24T07:04:45', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '7eb55940-6205-487c-96cf-6370dc63bf3a' User entered 'No (N)'	System	24 Oct 2020 12:05:02
	System	24 Oct 2020 12:05:02

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-10-24T07:04:50', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '7eb55940-6205-487c-96cf-6370dc63bf3a'	System	24 Oct 2020 12:05:02
User entered 'No (N)'	System	24 Oct 2020 12:05:02

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-10-24T07:04:55', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '7eb55940-6205-487c-96cf-6370dc63bf3a' User entered '24 Oct 2020 07:04:55'	System	24 Oct 2020 12:05:02
	System	24 Oct 2020 12:05:02

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 92'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-07T07:42:54', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'e6c569f9-7db7-44b1-b7de-44b766fb91d8'	System	07 Nov 2020 13:43:10
User entered 'No (N)'	System	07 Nov 2020 13:43:10

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-07T07:43:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'e6c569f9-7db7-44b1-b7de-44b766fb91d8'	System	07 Nov 2020 13:43:10
User entered 'No (N)'	System	07 Nov 2020 13:43:10

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-07T07:43:05', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'e6c569f9-7db7-44b1-b7de-44b766fb91d8' User entered '07 Nov 2020 07:43:05'	System	07 Nov 2020 13:43:10
	System	07 Nov 2020 13:43:10

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered 'Day 99'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-14T07:48:55', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'b9080a7a-5263-46c9-94de-284026ba1a5a'	System	14 Nov 2020 13:49:10
User entered 'No (N)'	System	14 Nov 2020 13:49:10

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-14T07:49:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'b9080a7a-5263-46c9-94de-284026ba1a5a'	System	14 Nov 2020 13:49:10
User entered 'No (N)'	System	14 Nov 2020 13:49:10

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-14T07:49:05', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'b9080a7a-5263-46c9-94de-284026ba1a5a' User entered '14 Nov 2020 07:49:05'	System	14 Nov 2020 13:49:10
	System	14 Nov 2020 13:49:10

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 19:28:51

US3032172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:48:57
Data entry locked.	System	10 Aug 2020 19:28:51
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 19:28:51

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-21T08:13:08', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '50877622-0256-4f39-ae95-1ce20df1d70f'	System	21 Nov 2020 14:13:59
User entered 'No (N)'	System	21 Nov 2020 14:13:59

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-21T08:13:53', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '50877622-0256-4f39-ae95-1ce20df1d70f'	System	21 Nov 2020 14:13:59
User entered 'No (N)'	System	21 Nov 2020 14:13:59

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-21T08:13:57', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '50877622-0256-4f39-ae95-1ce20df1d70f' User entered '21 Nov 2020 08:13:57'	System	21 Nov 2020 14:13:59
	System	21 Nov 2020 14:13:59

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-26T14:44:08', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '4ebc42c8-41ea-4e02-a4e7-7168c7affa7f' User entered 'No (N)'	System	26 Nov 2020 20:44:16
	System	26 Nov 2020 20:44:16

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-26T14:44:11', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '4ebc42c8-41ea-4e02-a4e7-7168c7affa7f' User entered 'No (N)'	System	26 Nov 2020 20:44:16
	System	26 Nov 2020 20:44:16

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-11-26T14:44:14', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '4ebc42c8-41ea-4e02-a4e7-7168c7affa7f' User entered '26 Nov 2020 14:44:14'	System	26 Nov 2020 20:44:16
	System	26 Nov 2020 20:44:16

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-02T06:05:25', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '2a234ec3-5b60-4dfa-8023-aebee6aa9a5f'	System	02 Dec 2020 12:05:34
User entered 'No (N)'	System	02 Dec 2020 12:05:34

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-02T06:05:28', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '2a234ec3-5b60-4dfa-8023-aebee6aa9a5f'	System	02 Dec 2020 12:05:34
User entered 'No (N)'	System	02 Dec 2020 12:05:34

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-02T06:05:32', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '2a234ec3-5b60-4dfa-8023-aebee6aa9a5f' User entered '02 Dec 2020 06:05:32'	System	02 Dec 2020 12:05:34
	System	02 Dec 2020 12:05:34

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-12T17:59:13', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '62321296-e44b-45b1-a6c8-b77fa3d4c8e0'	System	12 Dec 2020 23:59:22
User entered 'No (N)'	System	12 Dec 2020 23:59:22

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-12T17:59:16', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '62321296-e44b-45b1-a6c8-b77fa3d4c8e0' User entered 'No (N)'	System	12 Dec 2020 23:59:22
	System	12 Dec 2020 23:59:22

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-12T17:59:19', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '62321296-e44b-45b1-a6c8-b77fa3d4c8e0' User entered '12 Dec 2020 17:59:19'	System	12 Dec 2020 23:59:22
	System	12 Dec 2020 23:59:22

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 01:34:02
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'no AE needed' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:17:25
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 08:09:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-16T06:34:40', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '960a3750-b418-4b77-8164-89269da1d880'	System	16 Dec 2020 12:35:50
User entered 'Yes (Y)'	System	16 Dec 2020 12:35:50

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-16T06:34:44', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '960a3750-b418-4b77-8164-89269da1d880'	System	16 Dec 2020 12:35:50
User entered 'No (N)'	System	16 Dec 2020 12:35:50

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-16T06:34:50', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '960a3750-b418-4b77-8164-89269da1d880'	System	16 Dec 2020 12:35:50
User entered 'No (N)'	System	16 Dec 2020 12:35:50

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-16T06:35:02', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '960a3750-b418-4b77-8164-89269da1d880'	System	16 Dec 2020 12:35:50
User entered 'Yes (Y)'	System	16 Dec 2020 12:35:50

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-16T06:35:11', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '960a3750-b418-4b77-8164-89269da1d880'	System	16 Dec 2020 12:35:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 12:35:50

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-16T06:35:41', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '960a3750-b418-4b77-8164-89269da1d880' User entered '16 Dec 2020 06:35:41'	System	16 Dec 2020 12:35:50
	System	16 Dec 2020 12:35:50

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-23T06:04:37', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '64a6af39-5d90-4b94-95a8-1ba0a73bbde6'	System	23 Dec 2020 12:04:46
User entered 'No (N)'	System	23 Dec 2020 12:04:46

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-23T06:04:40', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '64a6af39-5d90-4b94-95a8-1ba0a73bbde6'	System	23 Dec 2020 12:04:46
User entered 'No (N)'	System	23 Dec 2020 12:04:46

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-23T06:04:43', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '64a6af39-5d90-4b94-95a8-1ba0a73bbde6' User entered '23 Dec 2020 06:04:43'	System	23 Dec 2020 12:04:46
	System	23 Dec 2020 12:04:46

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-30T05:53:06', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '6636689a-c849-412b-97bc-2dc517bb57db'	System	30 Dec 2020 11:53:16
User entered 'No (N)'	System	30 Dec 2020 11:53:16

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-30T05:53:10', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '6636689a-c849-412b-97bc-2dc517bb57db'	System	30 Dec 2020 11:53:16
User entered 'No (N)'	System	30 Dec 2020 11:53:16

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2020-12-30T05:53:13', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '6636689a-c849-412b-97bc-2dc517bb57db' User entered '30 Dec 2020 05:53:13'	System	30 Dec 2020 11:53:16
	System	30 Dec 2020 11:53:16

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-06T09:17:56', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'e8cd224b-0d81-4009-a31c-35774e9e040a' User entered 'No (N)'	System	06 Jan 2021 15:18:04
	System	06 Jan 2021 15:18:04

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-06T09:17:58', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'e8cd224b-0d81-4009-a31c-35774e9e040a'	System	06 Jan 2021 15:18:04
User entered 'No (N)'	System	06 Jan 2021 15:18:04

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-06T09:18:01', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'e8cd224b-0d81-4009-a31c-35774e9e040a' User entered '06 Jan 2021 09:18:01'	System	06 Jan 2021 15:18:04
	System	06 Jan 2021 15:18:04

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-13T06:21:12', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3084e825-0a3a-48fd-8c19-fa0a12fa4f90'	System	13 Jan 2021 12:21:23
User entered 'No (N)'	System	13 Jan 2021 12:21:23

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-13T06:21:18', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3084e825-0a3a-48fd-8c19-fa0a12fa4f90'	System	13 Jan 2021 12:21:23
User entered 'No (N)'	System	13 Jan 2021 12:21:23

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-13T06:21:21', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3084e825-0a3a-48fd-8c19-fa0a12fa4f90' User entered '13 Jan 2021 06:21:21'	System	13 Jan 2021 12:21:23
	System	13 Jan 2021 12:21:23

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-20T06:18:15', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'fb7dd799-64dd-482d-bc80-ad84e2e1b54f' User entered 'No (N)'	System	20 Jan 2021 12:18:27
	System	20 Jan 2021 12:18:27

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-20T06:18:21', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'fb7dd799-64dd-482d-bc80-ad84e2e1b54f'	System	20 Jan 2021 12:18:27
User entered 'No (N)'	System	20 Jan 2021 12:18:27

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-20T06:18:24', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'fb7dd799-64dd-482d-bc80-ad84e2e1b54f' User entered '20 Jan 2021 06:18:24'	System	20 Jan 2021 12:18:27
	System	20 Jan 2021 12:18:27

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-27T06:14:56', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '9e5d4541-4454-4248-ae19-6931854c27ab' User entered 'No (N)'	System	27 Jan 2021 12:15:08

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-27T06:14:59', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '9e5d4541-4454-4248-ae19-6931854c27ab' User entered 'No (N)'	System	27 Jan 2021 12:15:08
	System	27 Jan 2021 12:15:08

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-01-27T06:15:02', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '9e5d4541-4454-4248-ae19-6931854c27ab' User entered '27 Jan 2021 06:15:02'	System	27 Jan 2021 12:15:08
	System	27 Jan 2021 12:15:08

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-03T06:32:26', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '2a99805e-5fd6-4f89-9cda-c0feb9a1710c'	System	03 Feb 2021 12:32:36
User entered 'No (N)'	System	03 Feb 2021 12:32:36

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-03T06:32:30', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '2a99805e-5fd6-4f89-9cda-c0feb9a1710c'	System	03 Feb 2021 12:32:36
User entered 'No (N)'	System	03 Feb 2021 12:32:36

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-03T06:32:33', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '2a99805e-5fd6-4f89-9cda-c0feb9a1710c' User entered '03 Feb 2021 06:32:33'	System	03 Feb 2021 12:32:36
	System	03 Feb 2021 12:32:36

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-10T06:17:40', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ffcc5f65-68c9-4d2b-b9a9-17763464d865'	System	10 Feb 2021 12:17:49
User entered 'No (N)'	System	10 Feb 2021 12:17:49

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-10T06:17:43', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ffcc5f65-68c9-4d2b-b9a9-17763464d865'	System	10 Feb 2021 12:17:49
User entered 'No (N)'	System	10 Feb 2021 12:17:49

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-10T06:17:46', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'ffcc5f65-68c9-4d2b-b9a9-17763464d865' User entered '10 Feb 2021 06:17:46'	System	10 Feb 2021 12:17:49
	System	10 Feb 2021 12:17:49

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-17T05:37:27', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '1fd42f78-44f4-4557-9983-8b71adf6946d'	System	17 Feb 2021 11:37:37
User entered 'No (N)'	System	17 Feb 2021 11:37:37

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-17T05:37:31', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '1fd42f78-44f4-4557-9983-8b71adf6946d'	System	17 Feb 2021 11:37:37
User entered 'No (N)'	System	17 Feb 2021 11:37:37

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-17T05:37:34', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '1fd42f78-44f4-4557-9983-8b71adf6946d' User entered '17 Feb 2021 05:37:34'	System	17 Feb 2021 11:37:37
	System	17 Feb 2021 11:37:37

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-24T06:59:12-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '5a0c059e-d26a-46a0-b14c-d0c9dbe7fc62'	System	24 Feb 2021 11:59:21
User entered 'No (N)'	System	24 Feb 2021 11:59:21

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-24T06:59:15-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '5a0c059e-d26a-46a0-b14c-d0c9dbe7fc62'	System	24 Feb 2021 11:59:21
User entered 'No (N)'	System	24 Feb 2021 11:59:21

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-02-24T06:59:19-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '5a0c059e-d26a-46a0-b14c-d0c9dbe7fc62'	System	24 Feb 2021 11:59:21
User entered '24 Feb 2021 11:59:19'	System	24 Feb 2021 11:59:21

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-06T18:02:51-06:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '2095c0bd-2ef2-4caf-a4ed-85a85551660c'	System	07 Mar 2021 00:06:57
User entered 'No (N)'	System	07 Mar 2021 00:06:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-06T18:02:54-06:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '2095c0bd-2ef2-4caf-a4ed-85a85551660c'	System	07 Mar 2021 00:06:57
User entered 'No (N)'	System	07 Mar 2021 00:06:57

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-06T18:02:57-06:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '2095c0bd-2ef2-4caf-a4ed-85a85551660c'	System	07 Mar 2021 00:06:57
User entered '06 Mar 2021 18:02:57'	System	07 Mar 2021 00:06:57

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-10T02:16:48-06:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '67fb5b06-0570-4d03-abce-3045837b7759'	System	10 Mar 2021 08:16:57
User entered 'No (N)'	System	10 Mar 2021 08:16:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-10T02:16:50-06:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '67fb5b06-0570-4d03-abce-3045837b7759'	System	10 Mar 2021 08:16:57
User entered 'No (N)'	System	10 Mar 2021 08:16:57

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-10T02:16:53-06:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '67fb5b06-0570-4d03-abce-3045837b7759'	System	10 Mar 2021 08:16:57
User entered '10 Mar 2021 02:16:53'	System	10 Mar 2021 08:16:57

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-17T05:57:16-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'd10df036-737c-4ecd-a289-208d3cba74ea' User entered 'Yes (Y)'	System	17 Mar 2021 10:58:22
	System	17 Mar 2021 10:58:22

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-17T05:57:19-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'd10df036-737c-4ecd-a289-208d3cba74ea'	System	17 Mar 2021 10:58:22
User entered 'No (N)'	System	17 Mar 2021 10:58:22

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-17T05:57:23-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'd10df036-737c-4ecd-a289-208d3cba74ea'	System	17 Mar 2021 10:58:22
User entered 'No (N)'	System	17 Mar 2021 10:58:22

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-17T05:57:42-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'd10df036-737c-4ecd-a289-208d3cba74ea'	System	17 Mar 2021 10:58:22
User entered 'Yes (Y)'	System	17 Mar 2021 10:58:22

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-17T05:57:51-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'd10df036-737c-4ecd-a289-208d3cba74ea'	System	17 Mar 2021 10:58:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Mar 2021 10:58:22

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-17T05:58:10-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'd10df036-737c-4ecd-a289-208d3cba74ea' User entered '17 Mar 2021 05:58:10'	System	17 Mar 2021 10:58:22
	System	17 Mar 2021 10:58:22

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-24T07:02:40-04:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '73388941-7b2a-43cf-b496-dcbf674a17f8'	System	31 Mar 2021 11:19:27
User entered 'No (N)'	System	31 Mar 2021 11:19:27

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-24T07:02:43-04:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '73388941-7b2a-43cf-b496-dcbf674a17f8'	System	31 Mar 2021 11:19:27
User entered 'No (N)'	System	31 Mar 2021 11:19:27

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-24T07:02:46-04:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '73388941-7b2a-43cf-b496-dcbf674a17f8'	System	31 Mar 2021 11:19:27
User entered '24 Mar 2021 07:02:46'	System	31 Mar 2021 11:19:27

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-31T06:19:25-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '43180a5b-00c5-462c-935c-9817cab2f433'	System	31 Mar 2021 11:19:35
User entered 'No (N)'	System	31 Mar 2021 11:19:35

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-31T06:19:29-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '43180a5b-00c5-462c-935c-9817cab2f433'	System	31 Mar 2021 11:19:35
User entered 'No (N)'	System	31 Mar 2021 11:19:35

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-31T06:19:32-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '43180a5b-00c5-462c-935c-9817cab2f433'	System	31 Mar 2021 11:19:35
User entered '31 Mar 2021 06:19:32'	System	31 Mar 2021 11:19:35

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:25:43-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered 'Yes (Y)'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:25:49-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered 'No (N)'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:14-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered 'Yes (Y)'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244' User entered '0'	System	07 Apr 2021 10:28:57
	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '0'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '1'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244' User entered '0'	System	07 Apr 2021 10:28:57
	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '0'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '0'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '0'	System	07 Apr 2021 10:28:57

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '0'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '0'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244' User entered '0'	System	07 Apr 2021 10:28:57
	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '0'	System	07 Apr 2021 10:28:57

**US3032172**

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

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**Generated On: 11 Aug 2021 21:50:29**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '1'	System	07 Apr 2021 10:28:57

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '1'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '1'	System	07 Apr 2021 10:28:57

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '0'	System	07 Apr 2021 10:28:57

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '0'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:27:40-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered '1'	System	07 Apr 2021 10:28:57

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:28:03-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:28:18-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244'	System	07 Apr 2021 10:28:57
User entered 'No (N)'	System	07 Apr 2021 10:28:57

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-07T05:28:47-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '3794e2b1-e86d-4ff8-8837-d11854f58244' User entered '07 Apr 2021 05:28:47'	System	07 Apr 2021 10:28:57
	System	07 Apr 2021 10:28:57

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-16T12:14:58-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '16e61f3c-b974-48fb-94a3-b0c30d99a10b'	System	16 Apr 2021 17:18:22
User entered 'No (N)'	System	16 Apr 2021 17:18:22

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-16T12:15:00-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '16e61f3c-b974-48fb-94a3-b0c30d99a10b'	System	16 Apr 2021 17:18:22
User entered 'No (N)'	System	16 Apr 2021 17:18:22

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-16T12:15:02-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '16e61f3c-b974-48fb-94a3-b0c30d99a10b'	System	16 Apr 2021 17:18:22
User entered '16 Apr 2021 12:15:02'	System	16 Apr 2021 17:18:22

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-21T05:31:15-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c5334e65-ebaa-403b-823b-92d459da8f58'	System	28 Apr 2021 21:44:21
User entered 'No (N)'	System	28 Apr 2021 21:44:21

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-21T05:31:18-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c5334e65-ebaa-403b-823b-92d459da8f58'	System	28 Apr 2021 21:44:21
User entered 'No (N)'	System	28 Apr 2021 21:44:21

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-21T05:31:21-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'c5334e65-ebaa-403b-823b-92d459da8f58'	System	28 Apr 2021 21:44:21
User entered '21 Apr 2021 05:31:21'	System	28 Apr 2021 21:44:21

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-28T05:36:30-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'aba9a33d-f113-4c3c-91bb-0716f7e61cd4'	System	28 Apr 2021 21:44:21
User entered 'No (N)'	System	28 Apr 2021 21:44:21

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with 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 (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-28T05:36:33-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'aba9a33d-f113-4c3c-91bb-0716f7e61cd4'	System	28 Apr 2021 21:44:21
User entered 'No (N)'	System	28 Apr 2021 21:44:21

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-04-28T05:36:36-05:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: 'aba9a33d-f113-4c3c-91bb-0716f7e61cd4'	System	28 Apr 2021 21:44:21
User entered '28 Apr 2021 05:36:36'	System	28 Apr 2021 21:44:21

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:56:32

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US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:56:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 02:56:32

**US3032172**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:56:32
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 02:56:32

US3032172

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:50:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-06T18:03:04-06:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '4dd66445-e2e5-467b-a167-b6127f5f3adb'	System	10 Mar 2021 08:16:51
User entered 'No (N)'	System	10 Mar 2021 08:16:51

US3032172

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:50:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F58B556B-2016-4FBF-8455-0E8744DFCFAD)', Time: '2021-03-06T18:03:07-06:00', User OID: 'PatientReportedOutcome (US3032172)', ODM File OID: '4dd66445-e2e5-467b-a167-b6127f5f3adb' User entered '06 Mar 2021 18:03:07'	System	10 Mar 2021 08:16:51
	System	10 Mar 2021 08:16:51

US3032172

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:06:20
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 15:47:58

US3032172

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:06:20
User entered '13 Nov 2020'	Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 15:47:58

US3032172

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:06:20
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 15:47:58

US3032172

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:06:20
User entered empty.	Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 15:47:58

US3032172

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:06:23
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 15:48:03

US3032172

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:43:16
User entered '1'	System	01 Dec 2020 15:48:03

US3032172

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.		02 Apr 2021 18:31:59
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:24:49

US3032172

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.		02 Apr 2021 18:31:59
User closed query 'Per GCL Lab Reconciliation: Swab: Response to previous query, Sample Collection date is recorded as 03SEP2020 under Unscheduled in PPD central lab with accession number UNK00238460, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).		01 Feb 2021 10:26:10
Query 'Per GCL Lab Reconciliation: Swab: Response to previous query, Sample Collection date is recorded as 03SEP2020 under Unscheduled in PPD central lab with accession number UNK00238460, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' answered with 'sample was collected at unscheduled illness visit which occurred 01Sep2020' (Site from DM).	Samantha Wieseler (b) (4)	28 Jan 2021 15:16:55
User opened query 'Per GCL Lab Reconciliation: Swab: Response to previous query, Sample Collection date is recorded as 03SEP2020 under Unscheduled in PPD central lab with accession number UNK00238460, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 11:56:09
User closed query 'Per GCL Lab Reconciliation query: Swab: Per site response, "will update accordingly"; however, no updates are reflected in EDC. Kindly consider to update swab sample collected on 03-SEP-2020 by updating the Covid Diagnostic Test eCRF on Covid-19 Assessment for 03-SEP-2020 and consider to respond to query once the updates are made in EDC, else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 07:13:34

US3032172

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "will update accordingly"; however, no updates are reflected in EDC. Kindly consider to update swab sample collected on 03-SEP-2020 by updating the Covid Diagnostic Test eCRF on Covid-19 Assessment for 03-SEP-2020 and consider to respond to query once the updates are made in EDC, else clarify.' answered with 'no swab was collected on 03Sep2020. will update accordingly' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	21 Jan 2021 22:10:39
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "will update accordingly"; however, no updates are reflected in EDC. Kindly consider to update swab sample collected on 03-SEP-2020 by updating the Covid Diagnostic Test eCRF on Covid-19 Assessment for 03-SEP-2020 and consider to respond to query once the updates are made in EDC, else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:57:56
User closed query 'Per GCL Lab Reconciliation requery: Swab: Sample dated 03-SEP-2020 is reported under Unscheduled Visit in PPD portal; however, corresponding swab sample is missing in EDC for date 03-SEP-2020. Kindly review if swab sample was collected at unscheduled visit on 03-SEP-2020, if yes, consider initiating Covid-19 Assessment for 03-SEP-2020 & updating swab data in Covid Diagnostic Test eCRF, as we do not have provision to capture swab samples on Unscheduled eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:57:56
Query 'Per GCL Lab Reconciliation requery: Swab: Sample dated 03-SEP-2020 is reported under Unscheduled Visit in PPD portal; however, corresponding swab sample is missing in EDC for date 03-SEP-2020. Kindly review if swab sample was collected at unscheduled visit on 03-SEP-2020, if yes, consider initiating Covid-19 Assessment for 03-SEP-2020 & updating swab data in Covid Diagnostic Test eCRF, as we do not have provision to capture swab samples on Unscheduled eCRF, else clarify.' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	20 Jan 2021 22:24:29

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3032172

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation requery: Swab: Sample dated 03-SEP-2020 is reported under Unscheduled Visit in PPD portal; however, corresponding swab sample is missing in EDC for date 03-SEP-2020. Kindly review if swab sample was collected at unscheduled visit on 03-SEP-2020, if yes, consider initiating Covid-19 Assessment for 03-SEP-2020 & updating swab data in Covid Diagnostic Test eCRF, as we do not have provision to capture swab samples on Unscheduled eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:59:36
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 03SEP2020 under Unscheduled in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' (Site from DM).		20 Jan 2021 10:59:36
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 03SEP2020 under Unscheduled in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' answered with 'is under illness visit 1' (Site from DM).	Samantha Wieseler (b) (4)	19 Jan 2021 22:52:48
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 03SEP2020 under Unscheduled in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:45:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered '16 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:24:49

US3032172

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.		02 Apr 2021 18:31:59
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:24:49

US3032172

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.	(b) (4)	02 Apr 2021 18:31:59
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:24:49

US3032172

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.		02 Apr 2021 18:32:04
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:25:01

US3032172

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered '1'	System	17 Dec 2020 14:25:01

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Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.		02 Apr 2021 18:23:17
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	08 Mar 2021 23:14:21
	(b) (4)	

US3032172

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.	(b) (4)	02 Apr 2021 18:23:17
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
Signature has been broken.	(b) (4) Chelsie Nutsch (b) (4)	17 Mar 2021 14:53:54
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4) Chelsie Nutsch (b) (4)	17 Mar 2021 14:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered '18 Jan 2021'	(b) (4) Samantha Wieseler (b) (4)	08 Mar 2021 23:14:21
	(b) (4)	

US3032172

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.		02 Apr 2021 18:23:17
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	08 Mar 2021 23:14:21

US3032172

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.	(b) (4)	02 Apr 2021 18:23:17
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	08 Mar 2021 23:14:21
	(b) (4)	

US3032172

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.		02 Apr 2021 18:23:21
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	08 Mar 2021 23:14:27
	(b) (4)	

US3032172

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered '1'	System	08 Mar 2021 23:14:27

US3032172

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.		02 Apr 2021 18:23:00
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	08 Mar 2021 23:14:43

US3032172

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.		02 Apr 2021 18:23:00
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered '15 Feb 2021'	(b) (4) Samantha Wieseler (b) (4)	08 Mar 2021 23:14:43
	(b) (4)	

US3032172

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.		02 Apr 2021 18:23:00
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	08 Mar 2021 23:14:43

US3032172

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.	(b) (4)	02 Apr 2021 18:23:00
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered empty.	Samantha Wieseler (b) (4)	08 Mar 2021 23:14:43
	(b) (4)	

US3032172

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
DataPoint Verified.	(b) (4)	02 Apr 2021 18:23:09
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	08 Mar 2021 23:14:46
	(b) (4)	

US3032172

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered '1'	System	08 Mar 2021 23:14:46

US3032172

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:18
User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 01:48:20
Query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'not needed per protocol ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 18:24:20
User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:42:43
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:54:46

US3032172

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:18
User entered '19 Mar 2021'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:54:46

US3032172

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:18
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:54:46

US3032172

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered 'VISIT4'	System	19 Mar 2021 16:54:46

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:50
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered empty.	System	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered empty.	System	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered empty.	System	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered empty.	System	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered empty.	System	30 Mar 2021 19:39:23

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02

US3032172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02

US3032172

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:53
User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however physical examination performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 01:52:13
Query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however physical examination performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' answered with 'Visit 4 physical is symptom directed only. No physical was performed for visit 4, physical was done as part of OL-57' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	30 Mar 2021 15:01:28
User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however physical examination performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:43:07
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:55:07

US3032172

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:32:53
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:55:07

US3032172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
User closed query 'Per CDM Re-query: Per response visit 4 was drawn, however for "Was the sample collected?" is reported as " No" here, kindly review and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:53:22
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:33:14
Query 'Per CDM Re-query: Per response visit 4 was drawn, however for "Was the sample collected?" is reported as " No" here, kindly review and amend as appropriate.' answered with 'Blood sample was collected as part of OL-3 visit using corresponding kit ' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	01 Apr 2021 17:01:01
User opened query 'Per CDM Re-query: Per response visit 4 was drawn, however for "Was the sample collected?" is reported as " No" here, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 01:56:13
User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however immunogenicity assessment performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 01:56:13
Query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however immunogenicity assessment performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'visit 4 collected not OL3' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	30 Mar 2021 18:53:47
User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however immunogenicity assessment performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:43:27

US3032172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Was the sample collected?

Audit	User	Time (GMT)
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:55:24

US3032172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:33:14
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:55:24

US3032172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:33:14
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:55:24

US3032172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered empty.	System	19 Mar 2021 16:55:24

US3032172

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:33:18
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:55:28

US3032172

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:54:02
User entered '1'	System	19 Mar 2021 16:55:28

US3032172

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:22:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:54:08

US3032172

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:22:01
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:54:08

US3032172

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:22:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:54:08

US3032172

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:22:01
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:54:08

US3032172

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	22 Apr 2021 18:22:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:55:18

US3032172

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 15:55:18

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US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:50:29

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:13
User closed query 'Per CDM: it appears there are multiple records recorded in sequential date order. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:34:19
Query 'Per CDM: it appears there are multiple records recorded in sequential date order. Please reconcile and update accordingly.' answered with 'Records have been deactivated or cleared and waiting to be unactivated.' (Site from DM). DataPoint Verified.	Kelsey Kelley (b) (4) (b) (4)	10 Nov 2020 20:31:41
User opened query 'Per CDM: it appears there are multiple records recorded in sequential date order. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 12:53:05
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '01 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:30:26

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:50:29

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:13
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:55:33
User closed query 'Per the source call was conducted at 12:07 please update to reflect the source.' (Site from CRA).		11 Nov 2020 01:55:30
Query 'Per the source call was conducted at 12:07 please update to reflect the source.' answered with 'updated' (Site from CRA).	Kelsey Kelley (b) (4)	10 Nov 2020 20:30:30
Signature has been broken.	Kelsey Kelley (b) (4)	10 Nov 2020 20:30:24
User entered '12:07' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	10 Nov 2020 20:30:24
User opened query 'Per the source call was conducted at 12:07 please update to reflect the source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 12:52:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '08:00'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:30:26

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:50:29

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:13
User entered '01 Sep 2020 12:07'	System	10 Nov 2020 20:30:24
User entered '01 Sep 2020 08:00'	System	08 Sep 2020 23:30:26

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:50:29

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:13
DataPoint Verified.		05 Nov 2020 12:53:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:30:26

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:50:29

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:13
DataPoint Verified.	(b) (4)	05 Nov 2020 12:53:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:30:26
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User closed query 'Per ETRTR: Reporting of Symptoms are expected to be reported previous to Illness Visit Day 1. Please confirm Symptoms reported before 01Sep20, thanks.' (Site from CRA). User signature succeeded.	(b) (4)	07 Nov 2020 01:20:28
	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
	(b) (4)	
Query 'Per ETRTR: Reporting of Symptoms are expected to be reported previous to Illness Visit Day 1. Please confirm Symptoms reported before 01Sep20, thanks.' answered with 'day the subject report was same day subject came in for an illness visit' (Site from CRA).	Linden DeBoer (b) (4)	02 Oct 2020 17:09:19
	(b) (4)	
User opened query 'Per ETRTR: Reporting of Symptoms are expected to be reported previous to Illness Visit Day 1. Please confirm Symptoms reported before 01Sep20, thanks.' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 15:22:02
	(b) (4)	
User entered 'Day 1 (Day 1)'	Linden DeBoer (b) (4)	08 Sep 2020 23:32:56
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	17 Nov 2020 17:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:26:22
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:26:22
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:26:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:54:05
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '01 Sep 2020'	(b) (4)	
	Linden DeBoer (b) (4)	08 Sep 2020 23:32:56
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:43:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	17 Nov 2020 17:50:47
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:26:22
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:26:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
DataPoint Verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:26:22
	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	05 Nov 2020 12:55:17
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
	(b) (4)	
User entered '95'	Linden DeBoer (b) (4)	08 Sep 2020 23:32:56
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	17 Nov 2020 17:50:48
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:26:22
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:26:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
DataPoint Verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:26:22
	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	05 Nov 2020 12:55:14
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
	(b) (4)	
User entered '37.4' C	Linden DeBoer (b) (4)	08 Sep 2020 23:32:56
	(b) (4)	

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:51
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:32:56
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:52
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 22:40:21
DataPoint Verified.		5 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:32:56
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:54:23
User closed query 'Per the source sore throat symptom listed as moderate please update to reflect the source.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:54:21
Query 'Per the source sore throat symptom listed as moderate please update to reflect the source.' answered with 'updated' (Site from CRA).	Kelsey Kelley (b) (4) (b) (4)	10 Nov 2020 20:32:15
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	10 Nov 2020 18:26:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	10 Nov 2020 18:26:16
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User opened query 'Per the source sore throat symptom listed as moderate please update to reflect the source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 12:57:39
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
User entered 'Mild (Mild)'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:32:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 2 (Day 2)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:49:44

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:26:28
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:27:59
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:27:59
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered '02 Sep 2020'	Keith Vrbicky (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:49:44

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:26:45
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:27:59
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
User entered '95' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:27:59
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4), (b) (6)	08 Oct 2020 15:30:47
User entered '96'	Keith Vrbicky (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 12:49:44

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:26:55
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
User entered '99.4' F reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered '100.4' F	Linden DeBoer (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

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Form: Symptom Log (2)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:49:44

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:49:44

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:49:44

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:27:07
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered 'Mild (Mild)'	Linden DeBoer (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:49:44

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:27:12
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered 'None (None)'	Linden DeBoer (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:49:44

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:49:44
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:27:16
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:27:59
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:27:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:27:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4)	08 Oct 2020 12:49:44
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:49:44

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 3 (Day 3)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:52:28

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:27:34
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered '03 Sep 2020'	Linden DeBoer (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:27:41
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
User entered '96' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered '98'	Linden DeBoer (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 12:52:28

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:27:43
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
User entered '100.4' F reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered '98.6' F	Linden DeBoer (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:27:50
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered 'Mild (Mild)'	Linden DeBoer (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:52:28

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:52:28

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:52:28

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:52:28

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:52:28

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:52:28

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:52:28

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:52:28

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:27:54
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:29:07
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:29:07
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:29:07
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	Keith Vrbicky (b) (4)	08 Oct 2020 12:52:28
	(b) (4)	
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:52:28

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 4 (Day 4)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:28:21
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '04 Sep 2020'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:55:05

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:28:30
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:30:29
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User entered '98' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:30:29
DataPoint Verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User signature succeeded.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '100'	(b) (4)	08 Oct 2020 12:55:05
	Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 12:55:05

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '98.6' F	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:55:05

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:28:34
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:55:05

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:55:05

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:28:40
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered 'Mild (Mild)'	Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:28:46
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:30:29
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:30:29
DataPoint Verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User signature succeeded.	(b) (4)	05 Nov 2020 12:57:55
User entered 'Mild (Mild)'	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	08 Oct 2020 12:55:05
	Linden DeBoer (b) (4)	
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:28:51
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:55:05

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:28:59
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:30:29
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:30:29
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4), (b) (6)	(b) (4)
User entered 'None (None)'	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:55:05

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 12:55:05

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:29:06
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:29:08
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:30:29
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:30:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:30:29
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4), (b) (6)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 12:55:05
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 5 (Day 5)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:38:23

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:29:35
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered '05 Sep 2020'	Keith Vrbicky (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:29:43
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered '100' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered '96'	Keith Vrbicky (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 13:38:23

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:29:46
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered '98.6' F reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered '97.8' F	Linden DeBoer (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:29:48
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	Keith Vrbicky (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:29:53
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	Keith Vrbicky (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:29:55
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	Keith Vrbicky (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:29:59
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered 'None (None)'	Linden DeBoer (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:30:04
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:30:07
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	Keith Vrbicky (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:38:23

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:38:23

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 18:30:13
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:38:23

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:38:23

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:30:17
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:31:57
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:31:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:31:57
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	Keith Vrbicky (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:38:23
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 6 (Day 6)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:40:21

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Form: Symptom Log (6)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:30:30
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:32:56
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:32:56
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:32:56
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered '06 Sep 2020'	Keith Vrbicky (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	
	Linden DeBoer (b) (4)	
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:30:37
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:32:56
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:32:56
User entered '96' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:32:56
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4), (b) (6)	08 Oct 2020 15:30:47
User entered '99'	Keith Vrbicky (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 13:40:21

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:30:40
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:32:56
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:32:56
User entered '97.8' F reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:32:56
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered '98.6' F reason for change: Data Entry Error	Keith Vrbicky (b) (4)	08 Oct 2020 13:45:43
User entered '98.6' C	(b) (4)	08 Oct 2020 13:40:21
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:40:21

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:40:21

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:40:21

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:40:21

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:40:21

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:32:56
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:32:56
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:32:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:40:21

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:40:21

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:40:21

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 22:40:21
DataPoint Verified.		5 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:40:21
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 7 (Day 7)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:31:10
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:33:50
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:33:50
User entered '06 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:33:50
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered '07 Sep 2020'	Keith Vrbicky (b) (4)	08 Oct 2020 13:45:43
	(b) (4)	
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:45:43

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '99'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 13:45:43

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:31:18
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:33:50
User entered '98.6' F reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:33:50
User closed query 'Per the source the subjects temperature was 98 degrees Fahrenheit please update to reflect the source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:54:39
DataPoint Verified.	(b) (4)	11 Nov 2020 01:54:38
Query 'Per the source the subjects temperature was 98 degrees Fahrenheit please update to reflect the source.' answered with 'done' (Site from CRA).	Kelsey Kelley (b) (4) (b) (4)	10 Nov 2020 18:24:46
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	10 Nov 2020 18:24:28
User entered '98' F reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	10 Nov 2020 18:24:28
User opened query 'Per the source the subjects temperature was 98 degrees Fahrenheit please update to reflect the source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:03:32
DataPoint Un-verified.	(b) (4)	05 Nov 2020 18:01:57
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:30:47
User entered '98.1' F	Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:45:43

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:45:43

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:31:23
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:33:50
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:33:50
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:33:50
	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered 'Mild (Mild)'	Linden DeBoer (b) (4)	08 Oct 2020 13:45:43
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:45:43

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:45:43

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:31:30
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:33:50
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:33:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:33:50
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	Keith Vrbicky (b) (4)	08 Oct 2020 13:45:43
	(b) (4)	
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:45:43

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:45:43

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 8 (Day 8)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:31:48
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
User entered '07 Sep 2020' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '08 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:31:51
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
User entered '99' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '97'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:31:53
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
User entered '98.1' F reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '97.1' F	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:03
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Moderate (Moderate)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:32:09
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered 'None (None)'	Linden DeBoer (b) (4)	08 Oct 2020 13:48:48
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:48:48

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:32:17
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:35:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 13:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:48:48

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:48:48

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:48:48
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 9 (Day 9)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:50:41

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:32:36
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:35:58
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:35:58
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:35:58
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4), (b) (6)	08 Oct 2020 15:30:47
User entered '09 Sep 2020'	Keith Vrbicky (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	
	Linden DeBoer (b) (4)	
	(b) (4)	

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Form: Symptom Log (9)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:50:41

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:32:42
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:58
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:58
User entered '97' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:35:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '99'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:50:41

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 13:50:41

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:32:44
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:35:58
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:35:58
User entered '97.1' F reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:35:58
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered '98.2' F	Keith Vrbicky (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:50:41

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:32:52
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:35:58
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:35:58
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:35:58
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	Keith Vrbicky (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:32:56
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:35:58
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:35:58
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:35:58
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	Keith Vrbicky (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	
	Linden DeBoer (b) (4)	
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:50:41

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:50:41

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:50:41

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:50:41

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	

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Form: Symptom Log (9)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:50:41

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:50:41
	(b) (4)	

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Form: Symptom Log (10)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 10 (Day 10)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:52:19

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:33:15
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:37:51
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:37:51
User entered '09 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:37:51
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '10 Sep 2020'	(b) (4)	08 Oct 2020 13:52:19
	Linden DeBoer (b) (4)	
	(b) (4)	

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Form: Symptom Log (10)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:52:19

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:40:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:37:51
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:37:51
User entered '99' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:37:51
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4), (b) (6)	08 Oct 2020 15:30:47
User entered '97'	Keith Vrbicky (b) (4)	08 Oct 2020 13:52:19
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 13:52:19

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:40:40
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:37:51
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:37:51
User entered '98.2' F reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:37:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered '97.5' F	Linden DeBoer (b) (4)	08 Oct 2020 13:52:19
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:52:19

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:52:19

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:52:19
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:52:19

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Form: Symptom Log (10)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:52:19

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:52:19

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:52:19

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:52:19
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:52:19
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:52:19
	(b) (4)	

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:41:35
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:37:51
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:37:51
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:37:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 13:52:19
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:41:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:37:51
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:37:51
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:37:51
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	Keith Vrbicky (b) (4)	08 Oct 2020 13:52:19
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:52:19

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:52:19

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:52:19

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:52:19
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 11 (Day 11)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:53:49

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:42:05
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:38:35
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:38:35
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered '11 Sep 2020'	Keith Vrbicky (b) (4)	08 Oct 2020 13:53:49
	(b) (4)	
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:53:49
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:42:01
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:38:35
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
User entered '97' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:38:35
DataPoint Verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
User signature succeeded.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '98'	(b) (4)	08 Oct 2020 13:53:49
	Linden DeBoer (b) (4)	08 Oct 2020 13:53:49
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 13:53:49

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:42:03
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
User entered '97.5' F reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered '97.8' F	Linden DeBoer (b) (4)	08 Oct 2020 13:53:49
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:53:49
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:53:49
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:42:14
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 13:53:49
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:42:17
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:38:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered 'Mild (Mild)'	Linden DeBoer (b) (4)	08 Oct 2020 13:53:49
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:53:49
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:53:49

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 12 (Day 12)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:42:52
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:39:22
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:39:22
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:39:22
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered '12 Sep 2020'	Keith Vrbicky (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:39:22
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:39:22
User entered '98' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:39:22
DataPoint Verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:39:22
User signature succeeded.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '99'	(b) (4)	08 Oct 2020 13:55:14
	Linden DeBoer (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 13:55:14

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:48:49
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	11 Nov 2020 15:39:22
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:39:22
User entered '97.8' F reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:39:22
DataPoint Verified.	Linden DeBoer (b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	(b) (4)	08 Oct 2020 15:30:47
User entered '97.3' F	Keith Vrbicky (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	

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Form: Symptom Log (12)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:55:14

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:55:14

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:55:14

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:55:14

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	

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Form: Symptom Log (12)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:55:14

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:55:14

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:55:14

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:55:14

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Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:55:14

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	

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Form: Symptom Log (12)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	

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Form: Symptom Log (12)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:55:14
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:55:14

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Day 13 (Day 13)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:53:46
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
User entered '12 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:44:17
	(b) (4)	
User entered '13 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:40:53
	(b) (4)	
DataPoint Un-verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
	(b) (4)	
User entered '12 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered '13 Sep 2020'	Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 00:18:22
User closed query 'Per the source, the O2 on 12 Sep, was 99%. Please verify and correct if agreed.' (Site from CRA).		02 Apr 2021 00:18:20
Query 'Per the source, the O2 on 12 Sep, was 99%. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4)	22 Mar 2021 21:05:46
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	22 Mar 2021 21:05:27
User entered '99' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	22 Mar 2021 21:05:27
User opened query 'Per the source, the O2 on 12 Sep, was 99%. Please verify and correct if agreed.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 18:53:39
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
User entered '100' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:40:53
	(b) (4)	
DataPoint Un-verified.	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
	(b) (4)	
User entered '99' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered '100'	Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Form: Symptom Log (13)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	08 Oct 2020 13:56:46

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Form: Symptom Log (13)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
User closed query 'Per the source, the Temp on 12 Sep, was 97.3. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	02 Apr 2021 00:18:29
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 00:18:24
Query 'Per the source, the Temp on 12 Sep, was 97.3. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4)	22 Mar 2021 21:05:59
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	22 Mar 2021 21:05:27
User entered '97.3' F reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	22 Mar 2021 21:05:27
User opened query 'Per the source, the Temp on 12 Sep, was 97.3. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 18:54:31
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
User entered '97.6' F reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:40:53
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
User entered '97.3' F reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
	(b) (4)	
User entered '97.6' F	Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Form: Symptom Log (13)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:56:46

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Form: Symptom Log (13)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:56:46

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Form: Symptom Log (13)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Form: Symptom Log (13)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Form: Symptom Log (13)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:56:46

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Form: Symptom Log (13)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Form: Symptom Log (13)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Form: Symptom Log (13)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:56:46

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Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	02 Apr 2021 00:18:35
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint Un-verified.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:40:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Mild (Mild)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Oct 2020 13:56:46

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		05 Nov 2020 12:57:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	08 Oct 2020 13:56:46
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'Day 14 (Day 14)'	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:42:09
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:58:24
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered '13 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:44:17
User entered '14 Sep 2020'	Linden DeBoer (b) (4)	11 Nov 2020 15:42:09
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:58:27
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 18:58:28
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered '100'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
User closed query 'The source indicates a Temp of 97.6. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	02 Apr 2021 00:18:57
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 00:18:55
Query 'The source indicates a Temp of 97.6. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4)	22 Mar 2021 21:07:13
Signature has been broken.	(b) (4)	
User entered '97.6' F reason for change: Data Entry Error	Linden DeBoer (b) (4)	22 Mar 2021 21:06:56
User opened query 'The source indicates a Temp of 97.6. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	10 Mar 2021 18:58:21
User signature succeeded.	(b) (4), (b) (6)	
User entered '97.8' F	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:42:09
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 18:58:45
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
User closed query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	02 Apr 2021 07:11:14
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 00:19:04
Signature has been broken.	Linden DeBoer (b) (4)	22 Mar 2021 21:08:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	22 Mar 2021 21:08:12
Query 'The source indicates a value of Mild. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4)	22 Mar 2021 21:07:31
User opened query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	22 Mar 2021 21:07:31
User opened query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 18:59:20
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4)	11 Nov 2020 15:42:09
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:05:24
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		02 Apr 2021 07:11:44
User closed query 'The source indicates a value of None. Please verify and correct if agreed.' (Site from CRA).		02 Apr 2021 07:11:20
Query 'The source indicates a value of None. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:07:48
User opened query 'The source indicates a value of None. Please verify and correct if agreed.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:06:48
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	10 Dec 2020 16:21:22
User entered 'Mild (Mild)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	08 Dec 2020 20:00:38
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	08 Dec 2020 19:59:52
User entered 'None (None)' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	08 Dec 2020 19:59:52
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:51:00
User entered 'Mild (Mild)'	Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:06:55
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:06:57
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:07:00
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:07:02
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:07:07
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:07:09
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:07:12
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:07:18
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'Mild (Mild)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 07:11:37
User closed query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).		02 Apr 2021 07:11:35
Query 'The source indicates a value of Mild. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4)	22 Mar 2021 21:08:30
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	22 Mar 2021 21:06:56
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	22 Mar 2021 21:06:56
User opened query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:07:27
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
User entered 'None (None)'	Linden DeBoer (b) (4)	11 Nov 2020 15:42:09
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:07:31
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:07:34
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:07:37
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:42:09

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	
User entered 'Day 16 (Day 16)'	Linden DeBoer (b) (4)	11 Nov 2020 15:43:03
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:16:36
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:44:17
User entered '15 Sep 2020'	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:43:03
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:16:39
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User closed query 'The source indicates a value of 100%. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	13 Apr 2021 15:32:17
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 07:12:03
Query 'The source indicates a value of 100%. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:10:19
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:10:02
User entered '100' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:10:02
User opened query 'The source indicates a value of 100%. Please verify and correct if agreed.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:13:27
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:51:00
User entered '97'	Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User closed query 'The source indicates a value of 97.8. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	13 Apr 2021 15:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 07:12:03
Query 'The source indicates a value of 97.8. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:10:36
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:10:02
User entered '97.8' F reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:10:02
User opened query 'The source indicates a value of 97.8. Please verify and correct if agreed.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 19:15:14
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:51:00
User entered '96.8' F	Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:16:46
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:16:51
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
User closed query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	02 Apr 2021 07:12:28
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 07:12:03
Query 'The source indicates a value of Mild. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4)	22 Mar 2021 21:10:47
Signature has been broken.	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	22 Mar 2021 21:10:02
User opened query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	10 Mar 2021 19:15:43
User entered 'None (None)'	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:43:03
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
User closed query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	02 Apr 2021 07:12:30
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 07:12:03
Query 'The source indicates a value of Mild. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4)	22 Mar 2021 21:11:07
Signature has been broken.	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	22 Mar 2021 21:10:02
User opened query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	10 Mar 2021 19:15:52
User entered 'None (None)'	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:43:03
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
User closed query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	02 Apr 2021 07:12:32
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 07:12:03
Query 'The source indicates a value of Mild. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4)	22 Mar 2021 21:11:21
Signature has been broken.	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	22 Mar 2021 21:10:02
User opened query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	10 Mar 2021 19:16:18
User entered 'None (None)'	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:43:03
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:17:13
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:17:15
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:43:03
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:17:17
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:17:20
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:17:22
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
User closed query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	02 Apr 2021 07:12:47
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 07:12:03
Query 'The source indicates a value of Mild. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4)	22 Mar 2021 21:11:41
Signature has been broken.	(b) (4)	22 Mar 2021 21:10:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	22 Mar 2021 21:10:02
User opened query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	10 Mar 2021 19:17:29
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4)	11 Nov 2020 15:43:03
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
User closed query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	02 Apr 2021 07:12:48
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 07:12:03
Query 'The source indicates a value of Mild. Please verify and correct if agreed.' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4)	22 Mar 2021 21:11:55
Signature has been broken.	(b) (4)	22 Mar 2021 21:10:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	22 Mar 2021 21:10:02
User opened query 'The source indicates a value of Mild. Please verify and correct if agreed.' (Site from CRA).	(b) (4)	10 Mar 2021 19:17:37
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4)	11 Nov 2020 15:43:03
	Linden DeBoer (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:17:43
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:17:45
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:17:47
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:17:50
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	11 Nov 2020 15:43:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:45:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:44
	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:04
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Nov 2020 15:45:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 15:45:38
User entered '15 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	(b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Nov 2020 15:43:38
User entered empty.	System	11 Nov 2020 15:43:38
	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
DataPoint activated with code reason code Data required.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:43:44
User entered '0'	(b) (4) Linden DeBoer (b) (4)	11 Nov 2020 15:43:38

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
User entered '97' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:45:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:44
	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
User entered '%'	System	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	System	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '96.8' F reason for change: Data Entry Error	System	11 Nov 2020 15:45:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Linden DeBoer (b) (4)	11 Nov 2020 15:45:46
User entered '96.8' (non-conformant).	(b) (4)	
DataPoint activated with code reason code Data required.	System	11 Nov 2020 15:45:38
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	11 Nov 2020 15:45:38
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:43:44
	(b) (4)	
	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:45:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:44
	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.		10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	11 Nov 2020 15:45:38
	(b) (4)	
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:44
	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:21
DataPoint Verified.	(b) (4)	10 Mar 2021 19:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 15:45:38
DataPoint activated with code reason code Data required.	Linden DeBoer (b) (4)	11 Nov 2020 15:44:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	11 Nov 2020 15:43:44
User entered empty.	Linden DeBoer (b) (4)	11 Nov 2020 15:43:38
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:26
Query 'Per GCL Reconciliation: Swab sample collected on 01SEP2020 is labelled under "Unscheduled Visit Biofire" in Viracor data and in GCL it is labelled under "Illness D1". Please verify the correct visit for sample collected on this date.' canceled (Site from DM). DataPoint Verified.		17 Nov 2020 06:01:52
User opened query 'Per GCL Reconciliation: Swab sample collected on 01SEP2020 is labelled under "Unscheduled Visit Biofire" in Viracor data and in GCL it is labelled under "Illness D1". Please verify the correct visit for sample collected on this date.' (Site from DM).		05 Nov 2020 21:24:05
User closed query 'Per GCL Lab Recon: GCL appears to have an Unscheduled Swab dated 03SEP2020. Please review and reconcile or clarify' (Site from DM).		03 Nov 2020 09:22:04
Query 'Per GCL Lab Recon: GCL appears to have an Unscheduled Swab dated 03SEP2020. Please review and reconcile or clarify' answered with 'CORRECT AS ENTERED - FOR ILLNESS VISIT DAY 3' (Site from DM).	Russell Herstein (b) (4) (b) (4)	23 Oct 2020 08:36:41
User opened query 'Per GCL Lab Recon: GCL appears to have an Unscheduled Swab dated 03SEP2020. Please review and reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 02:02:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Oct 2020 18:58:31
User entered '1 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	28 Sep 2020 17:22:07
		08 Sep 2020 23:33:13

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:26
DataPoint Verified.		05 Nov 2020 21:23:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:33:13

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:26
DataPoint Verified.	(b) (4)	02 Apr 2021 07:13:06
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:50:57
User closed query 'Per CDM: Please complete Covid-19 Severity Assessment form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:24:43
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4)	12 Nov 2020 12:24:24
Query 'Per CDM: Please complete Covid-19 Severity Assessment form.' answered with 'form completed' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:49
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Is on AE form' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:01
User opened query 'Per CDM: Please complete Covid-19 Severity Assessment form.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 12:50:50
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	06 Nov 2020 15:55:08
DataPoint Un-verified.	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 15:55:08
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 15:55:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 15:55:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:24:33
DataPoint Un-verified.	(b) (4)	05 Nov 2020 21:24:23
DataPoint Verified.	(b) (4)	05 Nov 2020 21:24:21
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:33:13

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:26
DataPoint Verified.		05 Nov 2020 21:24:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '1 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:33:13

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:26
DataPoint Verified.	(b) (4)	05 Nov 2020 21:24:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:33:13

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:26
DataPoint Verified.		05 Nov 2020 21:24:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:33:13

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[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)	28 Apr 2021 22:40:26
DataPoint Verified.	(b) (4)	05 Nov 2020 21:24:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:33:13
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:26
DataPoint Verified.		08 Apr 2021 15:37:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:33:13

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:26
DataPoint Verified.	(b) (4)	08 Apr 2021 15:37:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:33:13

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:26
User entered '1'	System	06 Nov 2020 15:55:08
User entered '0'	System	08 Sep 2020 23:33:13

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:12
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:15
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:17
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:19
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:25
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:27
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:29
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:31
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Form: Covid-19 Severity Assessment

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:39
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:42
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.	(b) (4)	10 Mar 2021 18:02:44
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:02:46
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
User closed query 'Unable to verify where this is documented in the source. Please clarify where this is documented.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 07:13:39 02 Apr 2021 07:13:37
Query 'Unable to verify where this is documented in the source. Please clarify where this is documented.' answered with 'on Pg 2 of the illness Day 1 visit is a complete vitals section that can be used to calculate this.' (Site from CRA).	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:03:49
User opened query 'Unable to verify where this is documented in the source. Please clarify where this is documented.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 18:09:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.	(b) (4)	02 Apr 2021 07:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		02 Apr 2021 07:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		02 Apr 2021 07:13:54
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:03:45
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:03:51
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:03:55
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:03:59
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:01
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:04
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:05
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:07
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:10
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:14
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:20
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:22
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:24
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.	(b) (4)	10 Mar 2021 18:04:27
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:29
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.	(b) (4)	10 Mar 2021 18:04:34
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:37
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:43
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.	(b) (4)	10 Mar 2021 18:04:45
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:50
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:52
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:54
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:04:56
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:00
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:02
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:04
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:06
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:10
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:13
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:15
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

US3032172

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:17
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:20
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:22
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:32
DataPoint Verified.		10 Mar 2021 18:05:25
User signature succeeded.	Keith Vrbicky (b) (4)	17 Nov 2020 15:51:00
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Nov 2020 14:56:35

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:50:29

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:40:39
DataPoint Verified.		05 Nov 2020 21:24:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:30:46
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:50:29

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:14
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 07:16:38
Query 'Data is required. Please complete.' answered with 'data not needed on this page' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 07:16:38
Query 'Data is required. Please complete.' answered with 'data not needed on this page' (Site from System).	Linden DeBoer (b) (4)	08 Oct 2020 12:16:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Oct 2020 12:16:49
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 12:16:41
Signature has been broken.	Linden DeBoer (b) (4)	08 Oct 2020 12:16:41
User entered empty; reason for change Data Entry Error	(b) (4)	08 Oct 2020 12:16:41
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	08 Oct 2020 12:16:41
User signature succeeded.	(b) (4)	08 Oct 2020 12:16:41
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User signature succeeded.	(b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	08 Sep 2020 23:48:50
User entered 'Yes (Y)'	(b) (4)	08 Sep 2020 23:48:50

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05OCT2020 is reported under Unscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:33:28
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05OCT2020 is reported under Unscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'data correction as made' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 22:22:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05OCT2020 is reported under Unscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:56:49
User accepted default value 'Day 3 (Day 3)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:50:29

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:54:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:55
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User closed query 'Per GCL Lab Recon: it appears GCL has a Saliva sample with date of 10SEP2020 however it is not recorded in this log. Please reconcile and update accordingly or clarify' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:33:31
Query 'Per GCL Lab Recon: it appears GCL has a Saliva sample with date of 10SEP2020 however it is not recorded in this log. Please reconcile and update accordingly or clarify' answered with 'data correct as entered' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 22:22:50
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User opened query 'Per GCL Lab Recon: it appears GCL has a Saliva sample with date of 10SEP2020 however it is not recorded in this log. Please reconcile and update accordingly or clarify' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:43:10
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:54:52
User entered '3 Sep 2020'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User accepted default value 'Day 5 (Day 5)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F604309036 is reported with 09SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 06:24:40
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F604309036 is reported with 09SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with '09Sep2020 would not be Day 5. Will update in Preclarus' (Site from DM).	Samantha Wieseler (b) (4)	10 Feb 2021 14:16:07
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F604309036 is reported with 09SEP2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:44:28
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:54:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 19:46:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 19:46:44
User entered 'Yes (Y)' reason for change: New Information	Kelsey Kelley (b) (4)	15 Sep 2020 19:46:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 19:41:50
User entered empty.	System	15 Sep 2020 19:41:50
	Kelsey Kelley (b) (4)	15 Sep 2020 19:41:50
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05SEP2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 04:43:41
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05SEP2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Sample was shipped' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:26:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05SEP2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:53:27
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:54:52
User entered '5 Sep 2020' reason for change: New Information	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:46:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User accepted default value 'Day 7 (Day 7)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:54:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 19:46:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 19:46:44
User entered 'Yes (Y)' reason for change: New Information	Kelsey Kelley (b) (4)	15 Sep 2020 19:46:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 19:41:50
User entered empty.	System	15 Sep 2020 19:41:50
	Kelsey Kelley (b) (4)	15 Sep 2020 19:41:50
	(b) (4)	

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:54:52
User entered '7 Sep 2020' reason for change: New Information	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:46:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User accepted default value 'Day 9 (Day 9)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:54:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 19:46:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 19:46:44
User entered 'Yes (Y)' reason for change: New Information	Kelsey Kelley (b) (4)	15 Sep 2020 19:46:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 19:41:50
User entered empty.	System	15 Sep 2020 19:41:50
	Kelsey Kelley (b) (4)	15 Sep 2020 19:41:50
	(b) (4)	

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User closed query 'Per GCL LAB reconciliation Requery: Saliva: Confirm in response, if DAY5 - 05SEP2020 sample is reported with incorrect date 09SEP2020 in PPD and EDC- Day 9 - 09SEP2020 is reported with incorrect date 10SEP2020 in PPD. Please review the Preclarus data and amend the sample label in Preclarus and provide the correct date and sample label in response.' (Site from DM). Query 'Per GCL LAB reconciliation Requery: Saliva: Samantha Wieseler Confirm in response, if DAY5 - 05SEP2020 sample is reported with incorrect date 09SEP2020 in PPD and EDC- Day 9 - 09SEP2020 is reported with incorrect date 10SEP2020 in PPD. Please review the Preclarus data and amend the sample label in Preclarus and provide the correct date and sample label in response.' answered with 'will update in Preclarus' (Site from DM).	(b) (4), (b) (6) Samantha Wieseler (b) (4)	22 Jan 2021 10:19:19 20 Jan 2021 22:23:43
User opened query 'Per GCL LAB reconciliation Requery: Saliva: Confirm in response, if DAY5 - 05SEP2020 sample is reported with incorrect date 09SEP2020 in PPD and EDC- Day 9 - 09SEP2020 is reported with incorrect date 10SEP2020 in PPD. Please review the Preclarus data and amend the sample label in Preclarus and provide the correct date and sample label in response.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:14:41
User closed query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 10SEP2020 sample as Illness Visit Day 9, however there is no sample with the same date while Day 9 is on 09SEP2020 which is reported as DAY 5 in PPD and DAY 5 date in EDC is 05SEP2020 which is missing in PPD. Please review the PPD portal and confirm the correct date and correct label for each sample and if there is a mismatch update the EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:14:41

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL LAB reconciliation: Saliva: PPD lab Samantha Wieseler has a 10SEP2020 sample as Illness Visit Day 9, however there is no sample with the same date while Day 9 is on 09SEP2020 which is reported as DAY 5 in PPD and DAY 5 date in EDC is 05SEP2020 which is missing in PPD. Please review the PPD portal and confirm the correct date and correct label for each sample and if there is a mismatch update the EDC or PPD portal as appropriate. Thank you.' answered with 'will update accordingly' (Site from DM).	(b) (4)	19 Jan 2021 22:43:11
User opened query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 10SEP2020 sample as Illness Visit Day 9, however there is no sample with the same date while Day 9 is on 09SEP2020 which is reported as DAY 5 in PPD and DAY 5 date in EDC is 05SEP2020 which is missing in PPD. Please review the PPD portal and confirm the correct date and correct label for each sample and if there is a mismatch update the EDC or PPD portal as appropriate. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 09:00:26
User signature succeeded.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User entered '9 Sep 2020' reason for change: New Information	Keith Vrbicky (b) (4)	01 Oct 2020 21:54:52
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	15 Sep 2020 19:46:44
	(b) (4)	
	Kelsey Kelley (b) (4)	15 Sep 2020 19:41:50
	(b) (4)	

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User accepted default value 'Day 14 (Day 14)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:54:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 19:46:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 19:46:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	15 Sep 2020 19:46:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 19:41:50
User entered empty.	System	15 Sep 2020 19:41:50
	Kelsey Kelley (b) (4)	15 Sep 2020 19:41:50
	(b) (4)	

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:54:52
User entered '14 Sep 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:46:44
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User accepted default value 'Day 21 (Day 21)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 07:01:28
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 20:38:51
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:54:52
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 17:28:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 17:28:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 17:28:51
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 19:41:50
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 07:01:30
User closed query 'Per the source nasal / blood samples were collected please confirm if saliva was also collected as saliva is not listed in the source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:14:13
Query 'Per the source nasal / blood samples were collected please confirm if saliva was also collected as saliva is not listed in the source.' answered with 'yes' (Site from CRA).	Linden DeBoer (b) (4) (b) (4)	13 Nov 2020 13:17:25
User opened query 'Per the source nasal / blood samples were collected please confirm if saliva was also collected as saliva is not listed in the source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:09:48
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 20:38:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:54:52
User entered '21 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	01 Oct 2020 17:28:51
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User accepted default value 'Day 28 (Day 28)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:41:50

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
DataPoint Verified.		02 Apr 2021 06:59:31
DataPoint Un-verified.		05 Nov 2020 21:07:18
DataPoint Verified.		05 Nov 2020 21:07:11
DataPoint Un-verified.		05 Nov 2020 20:54:02
DataPoint Verified.		05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:54:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 17:28:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	01 Oct 2020 17:28:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	15 Sep 2020 19:41:50
	Kelsey Kelley (b) (4)	15 Sep 2020 19:41:50
	(b) (4)	

US3032172

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:24
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
User closed query 'Per the source no saliva was collected please clarify.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 06:59:37 02 Apr 2021 06:59:34
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05OCT2020 is recorded under Illness Visit Day 28 in EDC, however the data is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).		08 Dec 2020 04:58:45
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05OCT2020 is recorded under Illness Visit Day 28 in EDC, however the data is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Correct as entered' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 17:37:56
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05OCT2020 is recorded under Illness Visit Day 28 in EDC, however the data is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 07:00:52
Query 'Per the source no saliva was collected please clarify.' answered with 'data updated. Saliva was collected on Day 28 visit.' (Site from CRA). Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 22:21:42 24 Nov 2020 22:20:26
User entered '05 Oct 2020' reason for change: Data Entry Error DataPoint Un-verified.	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 22:20:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:14
User opened query 'Per the source no saliva was collected please clarify.' (Site from CRA).		05 Nov 2020 21:07:06

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per there was no saliva collected please clarify.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:06:43
User opened query 'Per there was no saliva collected please clarify.' (Site from CRA).		05 Nov 2020 21:06:36
DataPoint Un-verified.		05 Nov 2020 20:54:04
DataPoint Verified.		05 Nov 2020 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:54:52
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	01 Oct 2020 17:29:31
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	15 Sep 2020 19:41:50
	(b) (4)	

US3032172

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:28
DataPoint Verified.		05 Nov 2020 19:09:11
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:34:10

US3032172

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:28
DataPoint Verified.	(b) (4)	05 Nov 2020 19:09:11
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '1 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:34:10

US3032172

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:28
DataPoint Verified.		05 Nov 2020 19:09:11
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:34:10

US3032172

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:28
User entered 'SICKD1'	System	15 Sep 2020 19:34:10

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:17
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:15
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '1 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '14:30'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
User entered '1 Sep 2020 14:30'	System	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '177.8' cm	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 19:36:14
DataPoint set to visible.	(b) (4) System	15 Sep 2020 19:34:10

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '96.6' kg	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 19:36:14
DataPoint set to visible.	(b) (4) System	15 Sep 2020 19:34:10

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '37.4' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:45
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '82'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
User entered 'bpm'	System	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
User entered 'breaths/min'	System	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '136'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
User entered 'mmHg'	System	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
DataPoint Verified.		05 Nov 2020 19:10:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '82'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45
User entered 'mmHg'	System	15 Sep 2020 19:36:14

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45

US3032172

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:45

US3032172

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:50
DataPoint Verified.		05 Nov 2020 19:18:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:23

US3032172

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:50
DataPoint Verified.		05 Nov 2020 19:18:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '1 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:36:23

US3032172

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:50:29

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:54
DataPoint Verified.		05 Nov 2020 19:22:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:37:22

US3032172

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:08:54
DataPoint Verified.	(b) (4)	05 Nov 2020 19:22:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '1 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:37:22

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:06
DataPoint Verified.		05 Nov 2020 19:26:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:42:14

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:06
DataPoint Verified.	(b) (4)	05 Nov 2020 19:26:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '5 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:42:14

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:06
DataPoint Verified.		05 Nov 2020 19:26:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:42:14

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:06
User entered 'SICKD28'	System	05 Oct 2020 20:42:14

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.		05 Nov 2020 19:27:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	(b) (4)	
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	05 Oct 2020 20:43:08
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	05 Oct 2020 20:43:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	05 Oct 2020 20:43:08
User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	(b) (4)	
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	05 Oct 2020 20:43:03
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	05 Oct 2020 20:43:03
User entered 'No (N)'	Kelsey Kelley (b) (4)	05 Oct 2020 20:43:03
	(b) (4)	

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.	(b) (4)	05 Nov 2020 19:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '5 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.		05 Nov 2020 19:27:34
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '12:57'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
User entered '5 Oct 2020 12:57'	System	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.		05 Nov 2020 19:27:38
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '177.8' cm	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 20:43:03
DataPoint set to visible.	(b) (4) System	05 Oct 2020 20:42:14

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.		05 Nov 2020 19:27:41
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '96.4' kg	(b) (4) Kelsey Kelley (b) (4)	05 Oct 2020 20:43:03
DataPoint set to visible.	(b) (4) System	05 Oct 2020 20:42:14

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.	(b) (4)	05 Nov 2020 19:27:43
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	05 Oct 2020 20:43:19
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	05 Oct 2020 20:43:19
User entered '36.9' C reason for change: Data Entry Error	Kelsey Kelley (b) (4)	05 Oct 2020 20:43:19
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	05 Oct 2020 20:43:03
User entered '369.9' C	System	05 Oct 2020 20:43:03
	Kelsey Kelley (b) (4)	05 Oct 2020 20:43:03
	(b) (4)	

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.		05 Nov 2020 19:27:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.		05 Nov 2020 19:27:52
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.		05 Nov 2020 19:27:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '72'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
User entered 'bpm'	System	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.		05 Nov 2020 19:28:00
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
User entered 'breaths/min'	System	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.		05 Nov 2020 19:28:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '140'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
User entered 'mmHg'	System	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
DataPoint Verified.		05 Nov 2020 19:28:06
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '88'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10
User entered 'mmHg'	System	05 Oct 2020 20:43:03

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:10

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:15
DataPoint Verified.		05 Nov 2020 19:28:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:26

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:15
DataPoint Verified.		05 Nov 2020 19:28:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '5 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:26

US3032172

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:50:29

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:20
User closed query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 05OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).		19 Nov 2020 08:11:56
Query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 05OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'EDC CORRECT, LAB PORTAL UPDATED TO REFLECT. CENTRAL LAB DID NOT SUPPLY SITE WITH CORRECT KIT FOR CONV. VISIT DAY 28' (Site from DM).	Russell Herstein (b) (4) (b) (4)	18 Nov 2020 01:00:05
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:28:30
User opened query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 05OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).		28 Oct 2020 10:07:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Oct 2020 15:30:47
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:36

US3032172

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:09:20
DataPoint Verified.	(b) (4)	05 Nov 2020 19:28:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:30:47
User entered '5 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Oct 2020 20:43:36

US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(xxx.x\)](#)

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Audit	User	Time (GMT)
DataPoint set to visible.	System	05 Oct 2020 20:42:14

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US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(xxx.x\)](#)

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Audit	User	Time (GMT)
DataPoint set to visible.	System	05 Oct 2020 20:42:14

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US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(xxx.x\)](#)

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Audit	User	Time (GMT)
DataPoint set to visible.	System	05 Oct 2020 20:42:14

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US3032172

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(xxx.x\)](#)

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Audit	User	Time (GMT)
DataPoint set to visible.	System	05 Oct 2020 20:42:14

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US3032172

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

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:34:16
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:46:17
	(b) (4)	

US3032172

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

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:34:16
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '9 Jan 2021'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:46:17
	(b) (4)	

US3032172

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

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:34:16
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:46:17
	(b) (4)	

US3032172

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

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'UNBLND_DECIDE'	System	09 Jan 2021 19:46:17

US3032172

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

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:29
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '9 Jan 2021'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:46:33
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:06:32

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:29
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 12:05:24
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'subject got Diagnosed with COVID after 1st vaccine and did not get 2nd vaccine.' (Site from System).	Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:53:05
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	09 Jan 2021 19:52:32
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:46:33

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
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 12:06:32

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:29
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '9 Jan 2021'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:46:33
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:29
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Placebo (Placebo)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:46:33

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:29
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:51:41
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Placebo (Placebo)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:46:33

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:31:09
User entered 'Not Administered (NA)' reason for change: New Information	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:31:09
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered empty; reason for change Data Entry Error	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:32
User entered 'Placebo (Placebo)'	Linden DeBoer (b) (4)	09 Jan 2021 19:46:33
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:29
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	09 Jan 2021 19:48:21
User entered 'No (N)'	(b) (4)	
	Linden DeBoer (b) (4)	09 Jan 2021 19:46:33
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '1'	System	09 Feb 2021 18:31:09
User entered empty.	System	09 Jan 2021 19:52:32
User entered '1'	System	09 Jan 2021 19:46:33

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '1'	System	09 Feb 2021 18:31:09
User entered empty.	System	09 Jan 2021 19:52:32
User entered '1'	System	09 Jan 2021 19:48:21
User entered empty.	System	09 Jan 2021 19:46:33

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered missing code ND - Not Done.	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered missing code ND - Not Done.	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint set to visible.	System	09 Feb 2021 18:31:09
DataPoint set to invisible.	System	09 Jan 2021 19:52:32
User entered empty.	System	09 Jan 2021 19:52:22
DataPoint set to visible.	System	09 Jan 2021 19:48:21

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered missing code ND - Not Done.	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered missing code ND - Not Done.	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint set to visible.	System	09 Feb 2021 18:31:09
DataPoint set to invisible.	System	09 Jan 2021 19:52:32
User entered empty.	System	09 Jan 2021 19:52:22
DataPoint set to visible.	System	09 Jan 2021 19:48:21

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User accepted default value 'Pre-Dose (PREDOSE)'	Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '9 Jan 2021'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '11:26'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '9 Jan 2021 11:26'	System	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '36.9' C	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered empty.	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '70'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'bpm'	System	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '16'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'breaths/min'	System	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '130'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'mmHg'	System	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '78'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'mmHg'	System	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered missing code ND - Not Done.	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered missing code ND - Not Done.	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint set to visible.	System	09 Feb 2021 18:31:09
DataPoint set to invisible.	System	09 Jan 2021 19:52:32
User entered empty.	System	09 Jan 2021 19:52:22
DataPoint set to visible.	System	09 Jan 2021 19:48:21

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User accepted default value 'Post-Dose (POSTDOSE)'	Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '9 Jan 2021'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '13:10'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '9 Jan 2021 13:10'	System	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '36.8' C	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered empty.	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '63'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'bpm'	System	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '14'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'breaths/min'	System	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '121'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:52:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'mmHg'	System	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '83'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:52:22
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'mmHg'	System	09 Jan 2021 19:52:22

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:46
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:48:36
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:46
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '9 Jan 2021'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:48:36
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:49
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:49:43
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:49
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered empty.	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:49:43
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:49
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered empty.	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:49:43
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint set to visible.	System	09 Feb 2021 18:31:09
DataPoint set to invisible.	System	09 Jan 2021 19:52:32
User entered 'mRNA-1273'	System	09 Jan 2021 19:49:43
DataPoint set to visible.	System	09 Jan 2021 19:48:21

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:49
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '9 Jan 2021'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:49:43
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:49
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '12:36'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:49:43
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '9 Jan 2021 12:36'	System	09 Jan 2021 19:49:43

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:35:49
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Jan 2021 19:49:43

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:35:49
User entered 'ONCE'	System	09 Jan 2021 19:49:43

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'INTRAMUSCULAR'	System	09 Jan 2021 19:49:43

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:36:06
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:47:42
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:36:06
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '9 Jan 2021'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:47:42
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:36:06
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '11:04'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:47:42
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '9 Jan 2021 11:04'	System	09 Jan 2021 19:47:42

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:36:10
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:47:55
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:36:10
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '9 Jan 2021'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:47:55
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:36:10
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered '11:10'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:47:55
	(b) (4)	

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:50:29

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '9 Jan 2021 11:10'	System	09 Jan 2021 19:47:55

US3032172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:36:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:14
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Jan 2021 19:48:27
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '1'	System	09 Jan 2021 19:48:27

US3032172

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:36:16
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:30:11

US3032172

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:36:16
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '18 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:30:11

US3032172

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:36:16
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:30:11

US3032172

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:36:16
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:30:11

US3032172

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:36:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:30:14

US3032172

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '1'	System	09 Feb 2021 18:30:14

US3032172

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '1'	System	09 Feb 2021 18:30:14
DataPoint set to visible.	System	09 Feb 2021 18:30:14

US3032172

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:36:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:30:29

US3032172

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:36:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:30:29

US3032172

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:36:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:30:29

US3032172

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'OLD29'	System	09 Feb 2021 18:30:29

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '11:16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '9 Feb 2021 11:16'	System	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '37.0' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '64'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'bpm'	System	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'breaths/min'	System	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '136'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'mmHg'	System	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '85'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'mmHg'	System	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:33:02

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '12:12'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '9 Feb 2021 12:12'	System	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '62'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'bpm'	System	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'breaths/min'	System	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '122'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'mmHg'	System	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '80'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'mmHg'	System	09 Feb 2021 18:34:30

US3032172

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:32:39

US3032172

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:39:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:32:39

US3032172

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:41:15
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:31:41

US3032172

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:41:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:31:41

US3032172

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:41:21
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:31:41

US3032172

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User closed query 'Placebo is not an option in the Open Label phase; please choose the appropriate response.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:50:53
Query 'Placebo is not an option in the Open Label phase; please choose the appropriate response.' answered with 'This is a prefilled field. I am not able to fill in or change what is in this field. ' (Site from CRA).	Samantha Wieseler (b) (4) (b) (4)	13 Apr 2021 18:27:06
User opened query 'Placebo is not an option in the Open Label phase; please choose the appropriate response.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:53:34
User closed query 'Per the source the subject was dosed with MRNA-1273 please clarify ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:53:34
Query 'Per the source the subject was dosed with MRNA-1273 please clarify ' answered with 'subject received one dose of placebo during original visits. Will check source. ' (Site from CRA).	Samantha Wieseler (b) (4) (b) (4)	06 Apr 2021 16:19:53
User opened query 'Per the source the subject was dosed with MRNA-1273 please clarify ' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 18:40:58
User entered 'MRNA-1273 OR PLACEBO'	System	09 Feb 2021 18:31:41

US3032172

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:41:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '9 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:31:41

US3032172

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:41:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '11:39'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:31:41

US3032172

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '9 Feb 2021 11:39'	System	09 Feb 2021 18:31:41

US3032172

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:42:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:31:41

US3032172

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:43:00
User entered 'ONCE'	System	09 Feb 2021 18:31:41

US3032172

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 18:31:41

US3032172

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:43:12
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:32:07

US3032172

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '1'	System	09 Feb 2021 18:32:07

US3032172

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:38:05
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	08 Mar 2021 23:18:28
	(b) (4)	

US3032172

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:38:05
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered '16 Feb 2021'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	08 Mar 2021 23:18:28

US3032172

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:38:05
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	08 Mar 2021 23:18:28

US3032172

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.	(b) (4)	02 Apr 2021 18:38:05
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered empty.	Samantha Wieseler (b) (4)	08 Mar 2021 23:18:28
	(b) (4)	

US3032172

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
DataPoint Verified.		02 Apr 2021 18:38:10
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:35:52
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	08 Mar 2021 23:18:31
	(b) (4)	

US3032172

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '1'	System	08 Mar 2021 23:18:31

US3032172

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:36:50
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:42

US3032172

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:36:50
User entered '19 Mar 2021'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:42

US3032172

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:36:50
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:42

US3032172

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'OLD57'	System	19 Mar 2021 16:52:42

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:24
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:24
User entered '19 Mar 2021'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:24
User entered '10:09'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '19 Mar 2021 10:09'	System	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:24
User entered '36.7' C	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:24
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:24
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:24
User entered '73'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'bpm'	System	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:24
User entered '14'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'breaths/min'	System	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:24
User entered '121'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'mmHg'	System	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:24
User entered '72'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered 'mmHg'	System	19 Mar 2021 16:52:59

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05

US3032172

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05

US3032172

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:28
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:53:08

US3032172

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:28
User entered '19 Mar 2021'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:53:08

US3032172

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:48
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:53:32

US3032172

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:48
User entered '19 Mar 2021'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:53:32

US3032172

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:37:48
User entered '10:25'	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:53:32

US3032172

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:05
User entered '19 Mar 2021 10:25'	System	19 Mar 2021 16:53:32

US3032172

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:50:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:48:01
DataPoint Verified.	(b) (4)	02 Dec 2020 22:57:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	08 Sep 2020 23:58:12
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	11 Aug 2020 14:54:29
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:31:43
User entered 'USA-US032-2020-mRNA-1273-P301000002'	System	09 Sep 2020 18:29:31
User entered 'New'	(b) (4), (b) (6)	09 Sep 2020 18:29:31

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 00:00:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 00:00:58
Data point term sent to Coder	System	08 Sep 2020 23:59:55
User entered 'COVID 19'	Linden DeBoer (b) (4)	08 Sep 2020 23:59:31

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 23:59:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 23:59:58
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	08 Sep 2020 23:59:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 23:59:31
User entered empty.	System	08 Sep 2020 23:59:31
	Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User closed query 'PV Query: Please assess the start date of the event to when the subject started to experience signs and symptoms of Covid 19.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:01:36
Query 'PV Query: Please assess the start date of the event to when the subject started to experience signs and symptoms of Covid 19.' answered with 'data updated' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	02 Oct 2020 16:37:50
User entered '1 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	02 Oct 2020 16:37:42
User opened query 'PV Query: Please assess the start date of the event to when the subject started to experience signs and symptoms of Covid 19.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:52:06
User entered '8 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:58
User entered '2 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:31

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
User entered empty.	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:31

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 23:59:31

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US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User closed query 'PV Query: Please assess end date of the event. The subject remained with symptoms on 08 Sep 2020. Please consider updating event end date to when the subject has no COVID 19 symptoms. If to remain as 08 Sep 2020 please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:01:41
Query 'PV Query: Please assess end date of the event. The subject remained with symptoms on 08 Sep 2020. Please consider updating event end date to when the subject has no COVID 19 symptoms. If to remain as 08 Sep 2020 please state so.' answered with 'data entered' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	02 Oct 2020 16:37:58
User opened query 'PV Query: Please assess end date of the event. The subject remained with symptoms on 08 Sep 2020. Please consider updating event end date to when the subject has no COVID 19 symptoms. If to remain as 08 Sep 2020 please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:50:53
User entered '08 Sep 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:58
User entered '02 Sep 2020'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:31

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 23:59:31

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US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
User entered empty.	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:31

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
User entered empty.	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:31

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 02:08:33
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).		15 Sep 2020 19:58:42
User entered 'Not Related (NOT RELATED)'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:36:32
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:51
DataPoint Un-verified.	(b) (4)	08 Dec 2020 19:41:22
Signature has been broken.	Samantha Wieseler (b) (4)	08 Dec 2020 19:41:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 19:41:22
DataPoint Verified.	Samantha Wieseler (b) (4)	08 Dec 2020 19:41:22
User signature succeeded.	(b) (4)	02 Dec 2020 22:59:29
User signature succeeded.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Not Related (NOT RELATED)'	(b) (4)	08 Sep 2020 23:59:31
	Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		09 Nov 2020 07:41:09
User closed query 'Per DM CLR-RQ: Site's response noted. However, this information was not recorded on the Dosing Discontinuation page or End of Study/Study Discontinuation page. Please reconcile and update applicable eCRF pages as appropriate. Otherwise, clarify.' (Site from DM).		09 Nov 2020 07:41:07
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Covid-19 positive infection' (Site from System).	Chelsie Nutsch (b) (4) (b) (4)	07 Nov 2020 19:48:18
Query 'Per DM CLR-RQ: Site's response noted. However, this information was not recorded on the Dosing Discontinuation page or End of Study/Study Discontinuation page. Please reconcile and update applicable eCRF pages as appropriate. Otherwise, clarify.' answered with 'dosing discontinuation page completed per request' (Site from DM).	Chelsie Nutsch (b) (4) (b) (4)	07 Nov 2020 19:47:56
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	07 Nov 2020 19:47:15
User opened query 'Per DM CLR-RQ: Site's response noted. However, this information was not recorded on the Dosing Discontinuation page or End of Study/Study Discontinuation page. Please reconcile and update applicable eCRF pages as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 22:26:23
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:34:05
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' answered with 'since positive no second vax given per protocol' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	02 Oct 2020 16:38:15
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 21:00:37
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 14:21:07
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'data updated, next vaccine dose withdrawn' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:59:45
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 19:58:42
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:49:15
User entered 'None (NONE)'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:37:17
User closed query 'Per DM CLR: Other Action Taken = None. However, there are recorded ConMeds that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 19:40:21
Query 'Per DM CLR: Other Action Taken = None. However, there are recorded ConMeds that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 15:56:36
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	06 Nov 2020 15:56:27
User entered '0' reason for change: Data Entry Error	Linden DeBoer (b) (4)	06 Nov 2020 15:56:27
User opened query 'Per DM CLR: Other Action Taken = None. However, there are recorded ConMeds that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Oct 2020 22:26:50
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Sep 2020 23:59:58
User entered '1' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:58
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Sep 2020 23:59:31
User entered '0'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:37:17
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	06 Nov 2020 15:56:27
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	06 Nov 2020 15:56:27
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4)	
	Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:59:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:59:45
DataPoint Un-verified.		02 Dec 2020 22:59:35
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User closed query 'PV Query: Please report if the patient had any known exposure to covid and/or risk factors that would predispose to infection.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:02:48
User closed query 'PV Query: Please provide information regarding any treatment for the reported event.' (Site from Safety).		05 Oct 2020 14:02:38
User closed query 'PV Query: Please provide results of any other diagnostic studies done to evaluate the patient's symptoms.' (Site from Safety).		05 Oct 2020 14:02:00
User closed query 'PV Query: Please provide results of any additional COVID tests done following the negative test on 01-Sep-2020.' (Site from Safety).		05 Oct 2020 14:01:53
User closed query 'PV Query: Please confirm results of COVID 19 test at baseline.' (Site from Safety).		05 Oct 2020 14:01:48
Query 'PV Query: Please provide results of any additional COVID tests done following the negative test on 01-Sep-2020.' answered with 'Aug 10-baseline (-) Sep 10 illness visit- (+) Sep 21- visit 2- no vaccine- (+) Saliva collection turned negative on day 21 collection day ' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	02 Oct 2020 16:43:12
Query 'PV Query: Please provide information regarding any treatment for the reported event.' answered with 'na ' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	02 Oct 2020 16:39:04
Query 'PV Query: Please report if the patient had any known exposure to covid and/or risk factors that would predispose to infection.' answered with 'na' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	02 Oct 2020 16:38:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide results of any other diagnostic studies done to evaluate the patient's symptoms.' answered with 'na' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	02 Oct 2020 16:38:45
Query 'PV Query: Please confirm results of COVID 19 test at baseline.' answered with 'Negative' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	02 Oct 2020 16:38:32
User opened query 'PV Query: Please report if the patient had any known exposure to covid and/or risk factors that would predispose to infection.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:52:55
User opened query 'PV Query: Please provide information regarding any treatment for the reported event.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:52:42
User opened query 'PV Query: Please provide result of any other diagnostic studies done to evaluate the patient's symptoms.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:52:33
User opened query 'PV Query: Please provide result of any additional COVID tests done following the negative test on 01-Sep-2020.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:52:22
User opened query 'PV Query: Please confirm result of COVID 19 test at baseline.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 16:50:33
User entered empty.	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:59:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	08 Sep 2020 23:59:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 23:59:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:00:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.	(b) (4)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 00:02:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 00:02:58
Data point term sent to Coder	System	09 Sep 2020 00:02:16
User entered 'Upper Respiratory infection'	Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '31 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	09 Sep 2020 00:04:51
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Sep 2020 00:04:51
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Sep 2020 00:01:50
User entered '20:00'	Linden DeBoer (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
User entered empty.	System	09 Sep 2020 00:04:51
User entered '31 Aug 2020 20:00'	System	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '08 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	09 Sep 2020 00:04:51
User entered empty; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Sep 2020 00:04:51
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	09 Sep 2020 00:01:50
User entered '20:00'	Linden DeBoer (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
User entered empty.	System	09 Sep 2020 00:04:51
User entered '08 Sep 2020 20:00'	System	09 Sep 2020 00:01:50

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.	(b) (4)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.	(b) (4)	02 Apr 2021 18:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:51
DataPoint Un-verified.	(b) (4)	08 Dec 2020 19:42:07
Signature has been broken.	Samantha Wieseler (b) (4)	08 Dec 2020 19:42:07
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 19:42:07
DataPoint Verified.	Samantha Wieseler (b) (4)	08 Dec 2020 22:59:29
User signature succeeded.	(b) (4)	05 Oct 2020 16:15:05
User entered 'Not Related (NOT RELATED)'	Keith Vrbicky (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.	(b) (4)	02 Apr 2021 18:45:20
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:51
DataPoint Un-verified.	(b) (4)	(b) (4)
Signature has been broken.	Samantha Wieseler (b) (4)	08 Dec 2020 19:42:07
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	(b) (4)
DataPoint Verified.	Samantha Wieseler (b) (4)	08 Dec 2020 19:42:07
User signature succeeded.	(b) (4)	(b) (4)
User entered 'Not Related (NOT RELATED)'	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
	(b) (4)	(b) (4)
	Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	(b) (4)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Sep 2020 00:04:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 00:04:57
User entered 'None (NONE)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	09 Sep 2020 00:04:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Sep 2020 00:01:50
User entered empty.	System	09 Sep 2020 00:01:50
	Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '1'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

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 10:19:41
DataPoint Verified.		02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) Linden DeBoer (b) (4)	09 Sep 2020 00:01:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
DataPoint Verified.	(b) (4)	02 Dec 2020 22:59:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	09 Sep 2020 00:01:50

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
User entered '0'	System	09 Sep 2020 00:01:50

US3032172

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41
User entered '1'	System	09 Sep 2020 00:01:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User coded data point as SOC: Endocrine disorders, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	09 Feb 2021 18:37:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Feb 2021 18:37:34
Data point term sent to Coder	System	09 Feb 2021 18:36:14
User entered 'hypogonadism'	Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '16 Nov 2020'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '1'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:55:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:08
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:55:23
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:36:10

US3032172

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:50:29

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 18:36:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Secondary hypertension, LLT: Secondary hypertension - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	11 Feb 2021 21:15:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 21:15:56
Data point term sent to Coder	System	09 Feb 2021 18:38:15
User entered 'hypertension secondary to hypogonadism'	Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '3 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 18:38:00

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US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 18:38:00

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US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '1'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:55:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00
	(b) (4)	

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:44:44
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 18:38:00

US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 18:38:00

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US3032172

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:50:29

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 18:38:00

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US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.	(b) (4)	02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
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: Acid reflux (esophageal) - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Mar 2021 15:44:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 15:44:54
Data point term sent to Coder	System	17 Mar 2021 15:43:52
User entered 'acid reflux'	Kelsey Kelley (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.	(b) (4)	02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.	(b) (4)	02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '16 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
User entered empty.	System	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:43:59
Signature has been broken.	Kelsey Kelley (b) (4)	19 Mar 2021 16:53:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	19 Mar 2021 16:53:54
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:43:59
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Mar 2021 16:54:22
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Mar 2021 16:54:22
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Mar 2021 16:53:54
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:53:54
User entered '19 Mar 2021' reason for change: New Information	Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:13:55
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.	(b) (4)	02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
User entered empty.	System	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.	(b) (4)	02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '1'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:36:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:43:59
Signature has been broken.	Kelsey Kelley (b) (4)	19 Mar 2021 16:54:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Mar 2021 16:54:22
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

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 10:19:34
DataPoint Verified.		02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
DataPoint Verified.	(b) (4)	02 Apr 2021 18:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
User entered '0'	System	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34
User entered '1'	System	17 Mar 2021 15:43:00

US3032172

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:50:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:19:34

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:50:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:48:01
DataPoint Verified.		02 Dec 2020 22:53:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:42:03

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
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 - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 22:18:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 22:18:14
Data point term sent to Coder Coding entries removed.	System Samantha Wieseler (b) (4)	17 Sep 2020 21:25:28 17 Sep 2020 21:25:02
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 - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Aug 2020 07:02:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Aug 2020 07:02:20
Data point term sent to Coder User entered 'meloxicam'	System Kelsey Kelley (b) (4)	11 Aug 2020 14:43:33 11 Aug 2020 14:43:20

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:43:20

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'MEDICAL HISTORY: ARTHRALGIA-bilateral knees, hips, and shoulders' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	17 Sep 2020 21:25:02
User entered 'medical history: arthralgia'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:43:20

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '15'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:43:20

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:43:20
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:43:20
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:43:20

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:43:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:43:20
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:43:20
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:04:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 14:43:20
User entered 'un UNK 2010'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:43:20

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:43:20
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:43:20
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:43:20
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:43:20
	(b) (4)	

US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 14:43:20

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US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 14:43:20

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 14:43:20

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
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: GLUCOCORTICIDS, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Sep 2020 06:09:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Sep 2020 06:09:37
Data point term sent to Coder	System	17 Sep 2020 21:24:28
Data point term sent to Coder	System	17 Sep 2020 17:34:47
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	17 Sep 2020 17:34:03
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'spelling correct' (Site from System).	Kelsey Kelley (b) (4)	17 Sep 2020 17:34:03
User entered 'KENaLOG' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	17 Sep 2020 17:33:55
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	17 Aug 2020 05:18:16

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Aug 2020 14:51:46
Data point term sent to Coder	System	11 Aug 2020 14:49:44
User entered 'kenelog'	Kelsey Kelley (b) (4)	11 Aug 2020 14:49:41
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:49:41
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User closed query 'Per DM CLR: Please update the indication to reflect the location of ITCHING. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 11:26:20
Query 'Per DM CLR: Please update the indication to reflect the location of ITCHING. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	17 Sep 2020 21:24:25
User entered 'MEDICAL HISTORY: CHRONIC ITCHING bilateral hands' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	17 Sep 2020 21:24:20
User opened query 'Per DM CLR: Please update the indication to reflect the location of ITCHING. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 03:55:17
User entered 'MEDICAL HISTORY: CHRONIC ITCHING' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:50:49
User entered 'medical history: Itching'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:49:41

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '10'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:49:41
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:49:41

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'mg/mL'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:49:41

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:49:41

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'every four months'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:49:41

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'Intramuscular (INTRAMUSCULAR)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:49:41

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:49:41
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:04:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 14:49:41
User entered 'un UNK 2009'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:49:41

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:49:41

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:49:41

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:49:41
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:49:41

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 14:49:41

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 14:49:41

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 14:49:41

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIPILEPTICS, ATC: ANTIPILEPTICS, ATC: OTHER ANTIPILEPTICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Oct 2020 14:51:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Oct 2020 14:51:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 23:46:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 23:46:37
Data point term sent to Coder Coding entries removed.	System Samantha Wieseler (b) (4)	17 Sep 2020 21:25:28 17 Sep 2020 21:24:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Aug 2020 00:44:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Aug 2020 00:44:22
Data point term sent to Coder	System	11 Aug 2020 14:50:45
User entered 'gabapentin'	Kelsey Kelley (b) (4)	11 Aug 2020 14:50:35

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:50:35
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User closed query 'Per DM CLR: Please update the indication to reflect the location of ITCHING. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 11:26:34
Query 'Per DM CLR: Please update the indication to reflect the location of ITCHING. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	17 Sep 2020 21:24:40
User entered 'MEDICAL HISTORY: CHRONIC ITCHING bilateral hands' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	17 Sep 2020 21:24:35
User opened query 'Per DM CLR: Please update the indication to reflect the location of ITCHING. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 03:56:22
Query 'Per DM CLR: Please update the indication to reflect the location of ITCHING. Please reconcile with the AE and Med History eCRFs as appropriate. Per DM CLR: Please provide the actual dose for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate.'	(b) (4), (b) (6)	15 Sep 2020 03:56:01
' canceled (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 03:55:34
User opened query 'Per DM CLR: Please update the indication to reflect the location of ITCHING. Please reconcile with the AE and Med History eCRFs as appropriate. Per DM CLR: Please provide the actual dose for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate.'	(b) (4), (b) (6)	15 Sep 2020 03:55:34
' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 03:55:34
User entered 'medical history: chronic itching'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:50:35

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 11:26:41
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:42:25
User entered '300' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:42:09
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 03:55:59
User entered '1/2'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:50:35

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'mg (mg)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:42:09
User entered 'mL (mL)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:50:35

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:50:35
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:50:35

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:50:35
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:50:35

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:50:35
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:04:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 14:50:35
User entered 'un UNK 2009'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:50:35

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:50:35
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:50:35
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:50:35
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:50:35

US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 14:50:35

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US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 14:50:35

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 14:50:35

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Sep 2020 09:54:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Sep 2020 09:54:42
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	17 Sep 2020 17:42:00 17 Sep 2020 17:41:16
User entered 'TESTOSTERONE COMPOUND cream' reason for change: New Information	Kelsey Kelley (b) (4)	17 Sep 2020 17:41:16
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 21:15:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 21:15:14
Data point term sent to Coder	System	11 Aug 2020 14:51:47
User entered 'testosterone compound'	Kelsey Kelley (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'medical history: low testosterone'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name (e.g. Name of medication = TESTOSTERONE COMPOUND CREAM 1%, etc) and consider recording the number of applications instead in the dose and dose unit fields (e.g. Dose per administration=1; Dose Unit=application). Review and amend as appropriate.' (Site from DM). User signature succeeded.	(b) (4)	20 Oct 2020 12:40:54
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name (e.g. Name of medication = TESTOSTERONE COMPOUND CREAM 1%, etc) and consider recording the number of applications instead in the dose and dose unit fields (e.g. Dose per administration=1; Dose Unit=application). Review and amend as appropriate.' answered with 'updated' (Site from DM). Signature has been broken.	Keith Vrbicky (b) (4) (b) (4)	13 Oct 2020 13:52:29
User entered '1' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	09 Oct 2020 19:51:55
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name (e.g. Name of medication = TESTOSTERONE COMPOUND CREAM 1%, etc) and consider recording the number of applications instead in the dose and dose unit fields (e.g. Dose per administration=1; Dose Unit=application). Review and amend as appropriate.' (Site from DM). User signature succeeded.	Samantha Wieseler (b) (4) (b) (4)	09 Oct 2020 19:51:50
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate.' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	09 Oct 2020 19:51:50
	(b) (4) (b) (4), (b) (6)	08 Oct 2020 06:09:24
	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
	(b) (4), (b) (6)	28 Sep 2020 08:55:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate.  ' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:41:24
User entered '0.2' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:41:16
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of ml as there are other dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 03:56:45
User entered '1/2'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'Other (OTHER)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:41:16
User entered 'mL (mL)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:52:29
Signature has been broken.	(b) (4) Samantha Wieseler (b) (4)	09 Oct 2020 19:51:50
User entered 'application' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	09 Oct 2020 19:51:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '%' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	17 Sep 2020 17:41:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:51:36
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'Topical (TOPICAL)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:04:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 14:51:36
User entered 'un UNK 2014'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:51:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:51:36
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:51:36

US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 14:51:36

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US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 14:51:36

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US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 14:51:36

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:17:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:17:24
Data point term sent to Coder	System	11 Aug 2020 14:52:47
User entered 'loratide'	Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:52:02

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'medical history: seasonal allergies'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:52:02

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '10'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:52:02

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:04:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 14:52:02
User entered 'un UNK 2010'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 14:52:02

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:02

**US3032172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:50:29**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 14:52:02

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US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 14:52:02

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 14:52:02

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEP HRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL COLD & FLU - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 01:05:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 01:05:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 10:45:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 10:45:47
Data point term sent to Coder	System	17 Sep 2020 17:36:49
User entered 'dayquil (acetaminophen/dextromethorphan/phenylephrine)'	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'adverse event: sars-cov-2 infection'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '325/10/5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.	(b) (4)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.	(b) (4)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '02 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '15 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
User entered empty.	System	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
User entered empty.	System	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:24:28
User entered empty.	System	17 Sep 2020 17:36:26

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 10:48:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 10:48:44
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:53:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:12:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:12:24
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 09:48:19
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 Sep 2020 09:48:19
Data point term sent to Coder	System	17 Sep 2020 17:37:52

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
User entered 'nyquil (acetaminophen/dextromethorphan/doxylamine)'	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'adverse event: sars-cov-2 infection'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
Query 'Per DM CLR: Please review the recorded combination dose for this medication, as it seems this is not the standard combination dose. Please correct the dosage (i.e. 650/20/5) or provide explanation for alternate dosage. ' canceled (Site from DM).		08 Oct 2020 06:07:25
User opened query 'Per DM CLR: Please review the recorded combination dose for this medication, as it seems this is not the standard combination dose. Please correct the dosage (i.e. 650/20/5) or provide explanation for alternate dosage. ' (Site from DM).		08 Oct 2020 06:04:05
Query 'Per DM CLR: Please review the recorded combination dose for this medication, as it seems this is not the standard combination dose. Please correct the dosage (i.e. 650/20/12.5) or provide explanation for alternate dosage.		08 Oct 2020 06:03:19
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please review the recorded combination dose for this medication, as it seems this is not the standard combination dose. Please correct the dosage (i.e. 650/20/12.5) or provide explanation for alternate dosage.	(b) (4), (b) (6)	08 Oct 2020 06:03:05
' (Site from DM).		
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '650/30/12.5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '02 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '15 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
User entered empty.	System	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
User entered empty.	System	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:42:36
User entered empty.	System	17 Sep 2020 17:37:36

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.	(b) (4)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 17:39:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:39:43
Data point term sent to Coder	System	17 Sep 2020 17:38:54
User entered 'acetaminophen'	Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'adverse event: sars-cov-2 infection'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '1000'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'as needed (PRN)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.	(b) (4)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '02 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.	(b) (4)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 17:38:28
User entered '15 Sep 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	17 Sep 2020 17:38:28
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 17:38:19
User entered empty.	Kelsey Kelley (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
User entered empty.	System	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
User entered empty.	System	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:00:58
User entered empty.	System	17 Sep 2020 17:38:19

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.	(b) (4)	02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
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.	(b) (4) (b) (4) Coder Import (b) (4)	19 Oct 2020 20:42:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:42:33
Data point term sent to Coder	System	19 Oct 2020 20:41:31
User entered 'seasonal influenza vaccine'	Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	22 Oct 2020 14:49:44
User entered 'prophylaxis for seasonal influenza'	Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered '0.5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered 'mL (mL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered '9 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	19 Oct 2020 20:41:10
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered '9 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
DataPoint Verified.		02 Dec 2020 22:53:54
User signature succeeded.	Keith Vrbicky (b) (4)	22 Oct 2020 14:49:44
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
User entered empty.	System	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
User entered empty.	System	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:00
User entered empty.	System	19 Oct 2020 20:41:10

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.		02 Apr 2021 18:46:42
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE, PRODUCTSYNONYM: TESTOPEL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Feb 2021 18:40:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Feb 2021 18:40:34
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	09 Feb 2021 18:39:16 09 Feb 2021 18:39:09
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE, PRODUCTSYNONYM: TESTOPEL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Jan 2021 20:09:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Jan 2021 20:09:58
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	12 Jan 2021 20:09:31 12 Jan 2021 20:09:20
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE, PRODUCTSYNONYM: TESTOPEL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Dec 2020 16:54:15

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'testopel'	Coder Import (b) (4) System Kelsey Kelley (b) (4)	(b) (4) 17 Dec 2020 16:54:15 17 Dec 2020 16:52:37 17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.		02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.		02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:23
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening of LOW TESTOSTERONE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:57:03
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening of LOW TESTOSTERONE should be recorded, and update con med indication or provide clarification. ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:39:15
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:39:09
User entered 'hypogonadism' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:39:09
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening of LOW TESTOSTERONE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 00:39:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:49:49
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:58:34

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'data updated ' (Site from DM). Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 20:09:26
User entered 'TESTOSTERONE REPLACEMENT/Low testosterone' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 20:09:20
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	12 Jan 2021 16:18:07
User entered 'testosterone replacement'	Keith Vrbicky (b) (4) (b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Dec 2020 15:54:01 17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered '75'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered '16 Nov 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered '16 Nov 2020'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
User entered empty.	System	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
User entered empty.	System	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:15:05
User entered empty.	System	17 Dec 2020 16:51:38

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
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: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 11:56:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 11:56:58
Data point term sent to Coder Coding entries removed.	System Samantha Wieseler (b) (4)	15 Feb 2021 18:03:13 15 Feb 2021 18:02:50
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
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: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 16:54:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 16:54:15
Data point term sent to Coder User entered 'lisinopril'	System Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:52:37 17 Dec 2020 16:52:33

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:24:37
User closed query 'Per CDM , DM CLR re-query: Response noted , however please update the same indication in this field as added in the AE page else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 07:19:11
Query 'Per CDM , DM CLR re-query: Response noted , however please update the same indication in this field as added in the AE page else clarify. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:02:55
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:02:50
User entered 'HYPERTENSION secondary to hypogonadism' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 18:02:50
User opened query 'Per CDM , DM CLR re-query: Response noted , however please update the same indication in this field as added in the AE page else clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:49:47
User closed query 'Per CDM, DM CLR re-query: Response noted; however there is still no ongoing MH condition or AE that matches this Con Med indication. Please update to add the medical condition to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:49:47
Query 'Per CDM, DM CLR re-query: Response noted; however there is still no ongoing MH condition or AE that matches this Con Med indication. Please update to add the medical condition to the appropriate eCRF. ' answered with 'added ae information' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 18:38:35
User opened query 'Per CDM, DM CLR re-query: Response noted; however there is still no ongoing MH condition or AE that matches this Con Med indication. Please update to add the medical condition to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 14:18:00
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 14:17:52

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4)	19 Jan 2021 22:40:57
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:17:32
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'hypertension'	Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered '10'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:52:33

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	23 Dec 2020 15:54:01
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 16:52:33

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered '3 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:45:58
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:01
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 16:52:33

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 16:52:33

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US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 16:52:33

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Dec 2020 16:52:33

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
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: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 15:44:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 15:44:55
Data point term sent to Coder	System	17 Mar 2021 15:43:55
User entered 'omeprazole'	Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'acid reflux'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '20'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '16 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46
	(b) (4)	

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
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).		01 Apr 2021 01:18:42
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 'AE had stopped not a medication that is predicted to stop once there is a new baseline' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:12:55
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)	29 Mar 2021 09:45:48
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:13:55
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 15:43:46

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46

US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:45
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:13:55
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 15:43:46

US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:50:29**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 15:43:46

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US3032172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 15:43:46

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US3032172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 15:43:46

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US3032172

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:50:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:20:44
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 14:52:10
	(b) (4)	

US3032172

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:50:29

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:15
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:37:17
User entered '8 Sep 2020'	(b) (4) Chelsie Nutsch (b) (4)	07 Nov 2020 19:47:15

US3032172

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:50:29

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:59:15
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:37:17
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4) Chelsie Nutsch (b) (4)	07 Nov 2020 19:47:15
	(b) (4)	

US3032172

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:50:29

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 04:59:15
User signature succeeded.	Keith Vrbicky (b) (4)	08 Nov 2020 23:37:17
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	(b) (4) System	07 Nov 2020 19:47:27
User entered empty; reason for change Data Entry Error	Chelsie Nutsch (b) (4)	07 Nov 2020 19:47:27
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	(b) (4) System	07 Nov 2020 19:47:15
User entered 'Covid-19 positive infection'	Chelsie Nutsch (b) (4)	07 Nov 2020 19:47:15

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'USA-US032-2020-MRNA-1273-P301000002'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:26:41
Amendment Manager: User entered 'Keith'	System	14 Sep 2020 21:48:00

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:26:41
Amendment Manager: User entered 'Vrbicky'	System	14 Sep 2020 21:48:00

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
Un-reviewed for Safety.	System	05 Oct 2020 14:04:07
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered empty.	System	05 Oct 2020 14:04:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	21 Sep 2020 19:34:54

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
Reviewed for Safety.	(b) (4)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4)	21 Sep 2020 19:34:54
	(b) (4)	

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
Reviewed for Safety.	(b) (4)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4)	21 Sep 2020 19:34:54
	(b) (4)	

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
Un-reviewed for Safety.	System	05 Oct 2020 14:04:07
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered empty.	System	05 Oct 2020 14:04:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	21 Sep 2020 19:34:54

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:17:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 14:26:41
User entered 'US' (non-conformant).	System	09 Sep 2020 18:36:42

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbrick (b) (4)	05 Oct 2020 16:15:05
	(b) (4)	
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered '3'	System	05 Oct 2020 14:04:07
User signature succeeded.	Keith Vrbrick (b) (4)	28 Sep 2020 17:22:07
	(b) (4)	
User entered '2'	System	16 Sep 2020 14:26:55
User entered '1'	System	09 Sep 2020 18:36:42

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'USA-US032-2020-MRNA-1273-P301000002'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:26:41
Amendment Manager: User entered 'Keith'	System	14 Sep 2020 21:48:00

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:26:41
Amendment Manager: User entered 'Vrbicky'	System	14 Sep 2020 21:48:00

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
Un-reviewed for Safety.	System	05 Oct 2020 14:04:07
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered empty.	System	05 Oct 2020 14:04:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	21 Sep 2020 19:34:54

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
Reviewed for Safety.		05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4)	21 Sep 2020 19:34:54
	(b) (4)	

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
Reviewed for Safety.		05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4)	21 Sep 2020 19:34:54
	(b) (4)	

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
Un-reviewed for Safety.	System	05 Oct 2020 14:04:07
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered empty.	System	05 Oct 2020 14:04:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	21 Sep 2020 19:34:54

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:17:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 14:26:41
User entered 'US' (non-conformant).	System	09 Sep 2020 18:36:42

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbrick (b) (4)	05 Oct 2020 16:15:05
	(b) (4)	
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered '3'	System	05 Oct 2020 14:04:07
User signature succeeded.	Keith Vrbrick (b) (4)	28 Sep 2020 17:22:07
	(b) (4)	
User entered '2'	System	16 Sep 2020 14:26:55
User entered '1'	System	09 Sep 2020 18:36:42

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:50:29

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '09/Sep/2020 14:36'	(b) (4) System	09 Sep 2020 18:36:42

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:50:29

**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)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:26:41
User entered '1'		09 Sep 2020 18:36:42

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'USA-US032-2020-MRNA-1273-P301000002'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:26:41
Amendment Manager: User entered 'Keith'	System	14 Sep 2020 21:48:00

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:26:41
Amendment Manager: User entered 'Vrbicky'	System	14 Sep 2020 21:48:00

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
Un-reviewed for Safety.	System	05 Oct 2020 14:04:07
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered empty.	System	05 Oct 2020 14:04:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	21 Sep 2020 19:34:54

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
Reviewed for Safety.		05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4)	21 Sep 2020 19:34:54
	(b) (4)	

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
Reviewed for Safety.		05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4)	21 Sep 2020 19:34:54
	(b) (4)	

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
Un-reviewed for Safety.	System	05 Oct 2020 14:04:07
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered empty.	System	05 Oct 2020 14:04:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	21 Sep 2020 19:34:54

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:17:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 14:26:41
User entered 'US' (non-conformant).	System	09 Sep 2020 18:36:42

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbrick (b) (4)	05 Oct 2020 16:15:05
	(b) (4)	
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered '3'	System	05 Oct 2020 14:04:07
User signature succeeded.	Keith Vrbrick (b) (4)	28 Sep 2020 17:22:07
	(b) (4)	
User entered '2'	System	16 Sep 2020 14:26:55
User entered '1'	System	09 Sep 2020 18:36:42

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:50:29

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '16/Sep/2020 10:26'	(b) (4) System	16 Sep 2020 14:26:55

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:50:29

**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)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:26:55

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'USA-US032-2020-MRNA-1273-P301000002'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:36:36
User entered 'No (N)'	System	09 Sep 2020 18:29:31

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:26:41
Amendment Manager: User entered 'Keith'	System	14 Sep 2020 21:48:00

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:26:41
Amendment Manager: User entered 'Vrbicky'	System	14 Sep 2020 21:48:00

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
Un-reviewed for Safety.	System	05 Oct 2020 14:04:07
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered empty.	System	05 Oct 2020 14:04:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '1410 N 13th St'	Linden DeBoer (b) (4) (b) (4)	21 Sep 2020 19:34:54

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
Reviewed for Safety.		05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	21 Sep 2020 19:34:54

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
Reviewed for Safety.		05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
User entered empty.	(b) (4) Linden DeBoer (b) (4)	21 Sep 2020 19:34:54
	(b) (4)	

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	05 Oct 2020 16:15:05
Un-reviewed for Safety.	System	05 Oct 2020 14:04:07
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered empty.	System	05 Oct 2020 14:04:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 14:03:55
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
User entered '68701'	Linden DeBoer (b) (4) (b) (4)	21 Sep 2020 19:34:54

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:22:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:17:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 14:26:41
User entered 'US' (non-conformant).	System	09 Sep 2020 18:36:42

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
	(b) (4)	
Signature has been broken.	System	05 Oct 2020 14:04:07
User entered '3'	System	05 Oct 2020 14:04:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:22:07
	(b) (4)	
User entered '2'	System	16 Sep 2020 14:26:55
User entered '1'	System	09 Sep 2020 18:36:42

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:50:29

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '05/Oct/2020 14:04'	(b) (4) System	05 Oct 2020 14:04:07

US3032172

Folder: SAE USA-US032-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:50:29

**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)
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:57:16
User signature succeeded.	Keith Vrbicky (b) (4)	05 Oct 2020 16:15:05
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:04:07