

US3402194 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

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US3402194

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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Participant ID

US3402194

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

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US3402194

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 02 AUG 2020

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

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Folder OID SCRN

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US3402194

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	57
Age Units	YEARS
Age (Derived)	58
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



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 16:58:12

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Date of Informed Consent (*dd MMM yyyy*) 2 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

US3402194

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 16:58:12

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 16:58:12

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 16:58:12

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Condition	TYPE 1 DIABETES
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Start Year (derived)	1979
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN MAY 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:58:12

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Were vital signs assessed? Yes   
No

Date of assessment (*dd MMM yyyy*) 2 AUG 2020

Time of assessment (*00:00-23:59*) 16:15 (24 HR)

Vital Signs Date and Time (derived) 2 AUG 2020 16:15

Height (*xxx.x*) 160 cm

Weight (*xxx.x*) 99.7 kg

BMI (*xxx.x*) 38.94531 kg/m<sup>2</sup>

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral   
Axillary   
Other

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

Pulse (*xxx*) ND - Not Done

Pulse units BPM

Respiratory Rate (*xxx*) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) ND - Not Done

Diastolic Blood Pressure units MMHG

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

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

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:58:12

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

2 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:58:12

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**Occupational Risk**

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

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

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

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**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

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**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

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

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**Other** Yes  No

---

**Specify** NONE

---

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

---

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:58:12

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 2 AUG 2020

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

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Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 16:58:12

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What was the date of randomization? (dd MMM yyyy) 02 AUG 2020

What was the participant's randomization number? 142630

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 16:58:12

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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> )	2 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	16:15 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 16:15
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> )	78 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	56 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	2 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	17:27 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 17:27
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	73 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

2 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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) 2 AUG 2020

What was the treatment time? (00:00-23:59) 16:48 (24 HR)

Treatment Date and Time (derived) 2 AUG 2020 16:48

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 2 AUG 2020

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Collection time (*00:00-23:59*) 16:25 (24 HR)

---

Collection date and time (derived) 2 AUG 2020 16:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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Collection date ( <i>dd MMM yyyy</i> )			2 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	16:28	2 AUG 2020 16:28
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 02 AUG 2020 17:27

PC Open Date & Time 02 AUG 2020 17:08

PC Close Date & Time 02 AUG 2020 19:38

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	02 AUG 2020 22:45
PC Open Date & Time	02 AUG 2020 20:33
PC Close Date & Time	03 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**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	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 AUG 2020 09:14
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**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	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 AUG 2020 12:10
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

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

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

PC Time Stamp	05 AUG 2020 12:00
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes   
No

Please record your **TEMPERATURE** in °F \_\_\_\_\_  
Was any **MEDICATION TAKEN** today for pain or fever? Yes   
No

Please confirm reason for pain or fever medication (may select more than one):  
To **TREAT** pain or fever that has already occurred \_\_\_\_\_  
To **PREVENT** pain or fever from occurring \_\_\_\_\_  
PC Time Stamp \_\_\_\_\_  
PC Open Date & Time 06 AUG 2020 12:00  
PC Close Date & Time 07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**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	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 AUG 2020 12:12
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

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

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

PC Time Stamp	08 AUG 2020 12:52
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**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

02 AUG 2020 17:28

PC Open Date & Time

02 AUG 2020 17:08

PC Close Date & Time

02 AUG 2020 19:38

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**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	02 AUG 2020 22:46
PC Open Date & Time	02 AUG 2020 20:33
PC Close Date & Time	03 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**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	04 AUG 2020 09:15
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**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	04 AUG 2020 12:11
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59



US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**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	05 AUG 2020 12:00
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 5

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

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

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

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

PC Time Stamp

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**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

07 AUG 2020 12:12

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**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

08 AUG 2020 12:52

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

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

No

Yes

---

PC Time stamp	02 AUG 2020 17:28
PC Open Date & Time	02 AUG 2020 17:08
PC Close Date & Time	02 AUG 2020 19:38

---

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

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

No   
Yes

---

PC Time stamp	02 AUG 2020 22:47
PC Open Date & Time	02 AUG 2020 20:33
PC Close Date & Time	03 AUG 2020 11:59

---



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

---

	Yes <input type="checkbox"/>
PC Time stamp	04 AUG 2020 09:16
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

---

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

---

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

---

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

---

Yes

---

PC Time stamp	05 AUG 2020 12:01
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

---

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Yes

---

PC Time stamp

---

PC Open Date & Time

06 AUG 2020 12:00

---

PC Close Date & Time

07 AUG 2020 11:59

---



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

---

	Yes <input type="checkbox"/>
PC Time stamp	07 AUG 2020 12:13
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

---

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

---

	Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 12:52
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

---

US3402194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 AUG 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3402194

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:11

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3402194

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:11

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3402194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 AUG 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3402194

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

---

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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> )	2 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	15:07 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:07
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> )	88 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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> )	2 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	16:32 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 16:32
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> )	96 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG

US3402194

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

2 SEP 2020

---

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

---

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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) 2 SEP 2020

What was the treatment time? (00:00-23:59) 15:46 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 15:46

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

US3402194

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	2 SEP 2020
Collection time ( <i>00:00-23:59</i> )	15:32 (24 HR)
Collection date and time (derived)	2 SEP 2020 15:32

---



US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

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Collection date ( <i>dd MMM yyyy</i> )			02 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	15:36	02 SEP 2020 15:36
Nasopharyngeal Swab 2	No		

---

US3402194

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**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 98.6 °F

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

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

PC Time Stamp 02 SEP 2020 16:31

PC Open Date & Time 02 SEP 2020 16:06

PC Close Date & Time 02 SEP 2020 18:36

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp 02 SEP 2020 19:37  
PC Open Date & Time 02 SEP 2020 19:31  
PC Close Date & Time 03 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**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	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 SEP 2020 10:32
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**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	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	05 SEP 2020 10:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	05 SEP 2020 12:22
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**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	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 17:33
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59



US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**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	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 SEP 2020 20:32
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE in °F</b>	98.6 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	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	08 SEP 2020 12:02
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**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

02 SEP 2020 16:32

PC Open Date & Time

02 SEP 2020 16:06

PC Close Date & Time

02 SEP 2020 18:36

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**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	02 SEP 2020 19:37
PC Open Date & Time	02 SEP 2020 19:31
PC Close Date & Time	03 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**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	04 SEP 2020 10:32
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**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	05 SEP 2020 10:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**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	05 SEP 2020 12:22
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**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	06 SEP 2020 17:33
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59



US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**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	07 SEP 2020 20:32
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**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	08 SEP 2020 12:02
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

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

No

Yes

---

PC Time stamp	02 SEP 2020 16:32
PC Open Date & Time	02 SEP 2020 16:06
PC Close Date & Time	02 SEP 2020 18:36

---

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

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

No

Yes

---

PC Time stamp	02 SEP 2020 19:38
PC Open Date & Time	02 SEP 2020 19:31
PC Close Date & Time	03 SEP 2020 11:59

---

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

---

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 10:32
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

---



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

---

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 10:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

---

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

---

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 13:13
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

---

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

---

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 17:33
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

---

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

---

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 20:33
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

---



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**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

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

---

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 12:02
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

---

US3402194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 SEP 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3402194

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3402194

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3402194

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3402194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 30 SEP 2020

---

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

---

Folder OID VISIT3

---

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) 30 SEP 2020

Time of assessment (00:00-23:59) 14:11 (24 HR)

Vital Signs Date and Time (derived) 30 SEP 2020 14:11

Temperature (xxx.x) 36.8 C

Route of measurement Oral   
Axillary   
Other

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

Pulse (xxx) 84 beats/min

Pulse units BPM

Respiratory Rate (xxx) 14 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 127 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 61 mmHg

Diastolic Blood Pressure units MMHG

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

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

US3402194

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

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.*

---

US3402194

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	30 SEP 2020
Collection time ( <i>00:00-23:59</i> )	14:16 (24 HR)
Collection date and time (derived)	30 SEP 2020 14:16

---

US3402194

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:58:12

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	02 OCT 2020 00:05:16
Patient Cloud Open Date & Time	02 OCT 2020 00:01
Patient Cloud Close Date & Time	06 OCT 2020 23:59

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

Yes

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

No

Yes

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

Date and time of submission 09 OCT 2020 00:02:01

Patient Cloud Open Date & Time 09 OCT 2020 00:01

Patient Cloud Close Date & Time 13 OCT 2020 23:59

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 16 OCT 2020 00:01:48

Patient Cloud Open Date & Time 16 OCT 2020 00:01

Patient Cloud Close Date & Time 20 OCT 2020 23:59



US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	03 NOV 2020 12:32:04
Patient Cloud Open Date & Time	30 OCT 2020 00:01
Patient Cloud Close Date & Time	03 NOV 2020 23:59

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	06 NOV 2020 00:02:13
Patient Cloud Open Date & Time	06 NOV 2020 00:01
Patient Cloud Close Date & Time	10 NOV 2020 23:59

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT** DAY 106

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

Have you been exposed to someone with known SARS-CoV-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) True

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 False

Congestion False

Runny nose False

Nausea False

Vomiting True

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

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

Date and time of submission 13 NOV 2020 09:02:17

Patient Cloud Open Date & Time 13 NOV 2020 00:01

PRODUCTION RELEASE (v12.003 EAB) (1725)

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US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

---

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

---

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 110

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

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

17 NOV 2020 00:01

---

[Patient Cloud Close Date & Time](#)

21 NOV 2020 23:59

---

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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 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 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"/>
Have 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	25 NOV 2020 07:51:13
Patient Cloud Open Date & Time	24 NOV 2020 00:01
Patient Cloud Close Date & Time	28 NOV 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 12:00:43
Patient Cloud Open Date & Time	01 DEC 2020 00:01
Patient Cloud Close Date & Time	05 DEC 2020 23:59



US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 131

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

No

Yes

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

No

Yes

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

Date and time of submission 12 DEC 2020 11:59:27

Patient Cloud Open Date & Time 08 DEC 2020 00:01

Patient Cloud Close Date & Time 12 DEC 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 138

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

No

Yes

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

No

Yes

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

Date and time of submission 17 DEC 2020 17:10:49

Patient Cloud Open Date & Time 15 DEC 2020 00:01

Patient Cloud Close Date & Time 19 DEC 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 145

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

No

Yes

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

No

Yes

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

Date and time of submission 22 DEC 2020 00:06:56

Patient Cloud Open Date & Time 22 DEC 2020 00:01

Patient Cloud Close Date & Time 26 DEC 2020 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	29 DEC 2020 21:52:00
Patient Cloud Open Date & Time	29 DEC 2020 00:01
Patient Cloud Close Date & Time	02 JAN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	08 JAN 2021 18:00:58
Patient Cloud Open Date & Time	05 JAN 2021 00:01
Patient Cloud Close Date & Time	09 JAN 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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**TIMEPOINT**

DAY 166

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

No

Yes

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Have you been exposed to someone with known SARS-CoV-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):

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Date and time of submission

12 JAN 2021 00:08:37

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Patient Cloud Open Date & Time

12 JAN 2021 00:01

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Patient Cloud Close Date & Time

16 JAN 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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 22 JAN 2021 16:54:15

Patient Cloud Open Date & Time 19 JAN 2021 00:01

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

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	28 JAN 2021 12:06:18
Patient Cloud Open Date & Time	26 JAN 2021 00:01
Patient Cloud Close Date & Time	30 JAN 2021 23:59



US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	03 FEB 2021 10:56:23
Patient Cloud Open Date & Time	02 FEB 2021 00:01
Patient Cloud Close Date & Time	06 FEB 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	12 FEB 2021 17:38:25
Patient Cloud Open Date & Time	09 FEB 2021 00:01
Patient Cloud Close Date & Time	13 FEB 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 201

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

No

Yes

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

No

Yes

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

Date and time of submission 16 FEB 2021 00:25:39

Patient Cloud Open Date & Time 16 FEB 2021 00:01

Patient Cloud Close Date & Time 20 FEB 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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 23 FEB 2021 00:13:50

Patient Cloud Open Date & Time 23 FEB 2021 00:01

Patient Cloud Close Date & Time 27 FEB 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	02 MAR 2021 02:53:08
Patient Cloud Open Date & Time	02 MAR 2021 00:01
Patient Cloud Close Date & Time	06 MAR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 222

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAR 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 229

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

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

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



**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAR 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 236

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

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 243

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

No

Yes

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

No

Yes

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

Date and time of submission 30 MAR 2021 00:11:22

Patient Cloud Open Date & Time 30 MAR 2021 00:01

Patient Cloud Close Date & Time 03 APR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	06 APR 2021 00:08:48
Patient Cloud Open Date & Time	06 APR 2021 00:01
Patient Cloud Close Date & Time	10 APR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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	13 APR 2021 11:11:34
Patient Cloud Open Date & Time	13 APR 2021 00:01
Patient Cloud Close Date & Time	17 APR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 APR 2021 12:13:58
Patient Cloud Open Date & Time	20 APR 2021 00:01
Patient Cloud Close Date & Time	24 APR 2021 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 APR 2021 10:38:51
Patient Cloud Open Date & Time	27 APR 2021 00:01
Patient Cloud Close Date & Time	01 MAY 2021 23:59



US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 2021 00:01

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[Patient Cloud Close Date & Time](#) 05 JUN 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 2021 00:01

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[Patient Cloud Close Date & Time](#) 12 JUN 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 JUN 2021 00:01

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19 JUN 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3402194**

**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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22 JUN 2021 00:01

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26 JUN 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

**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](#)

29 JUN 2021 00:01

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03 JUL 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 341

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

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

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**Generated On: 09 Jun 2021 17:27:28**

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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 2021 00:01

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10 JUL 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 2021 00:01

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17 JUL 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 JUL 2021 00:01

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24 JUL 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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>	03 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 AUG 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 10 AUG 2021 00:01

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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Date and time of submission

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17 AUG 2021 00:01

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21 AUG 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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>	31 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 SEP 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 OCT 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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>	05 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 OCT 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 OCT 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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02 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 NOV 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 NOV 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 DEC 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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>	07 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 DEC 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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>	14 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 DEC 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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](#)

21 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 DEC 2021 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JAN 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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[Patient Cloud Close Date & Time](#)

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29 JAN 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 FEB 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#) 12 FEB 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#) 19 FEB 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#) 12 MAR 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 MAR 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 600

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

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**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 MAR 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 APR 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#) 07 MAY 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 24 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#) 28 MAY 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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](#)

31 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#) 11 JUN 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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>	14 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUN 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUN 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JUL 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 JUL 2022 00:01

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

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2022 23:59

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JUL 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#) 30 JUL 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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>	02 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 AUG 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

---

Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

---

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	16 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 AUG 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 AUG 2022 23:59

---

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 SEP 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 SEP 2022 23:59

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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

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US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**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

**US3402194**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

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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](#) 04 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#) 08 OCT 2022 23:59

---

US3402194

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:27:28

---

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		02 MAR 2021 02:53:57

---

US3402194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:19:37

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---



US3402194

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:19:37

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

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 SUBJECT IN CONVALESCENT  
PHASE

---

*If Contact Not Made, please provide Comments*

---

US3402194

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3402194

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 JAN 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3402194

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 2 MAR 2021

---

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

---

Folder OID VISIT4

---



US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

Were vital signs assessed? Yes   
No

Date of assessment (*dd MMM yyyy*) 02 MAR 2021

Time of assessment (*00:00-23:59*) 12:11 (24 HR)

Vital Signs Date and Time (derived) 02 MAR 2021 12:11

Temperature (*xxx.x*) 36.5 C

Route of measurement Oral   
Axillary   
Other

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

Pulse (*xxx*) 74 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 125 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 65 mmHg

Diastolic Blood Pressure units MMHG

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

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

US3402194

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

2 MAR 2021

---

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

---

US3402194

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 2 MAR 2021

---

Collection time (*00:00-23:59*) 12:29 (24 HR)

---

Collection date and time (derived) 2 MAR 2021 12:29

---

US3402194

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 MAR 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3402194

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

**US3402194**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:28**

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* \_\_\_\_\_

**US3402194**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:28**

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

Date of Contact	13 NOV 2020
Time of Contact	11:30
Date and Time of Contact (derived)	13 NOV 2020 11:30
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/> Clinical Visit - Unscheduled <input type="radio"/> Safety Call <input type="radio"/> Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/> No <input type="radio"/>

---

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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 NOV 2020
------	-------------

---

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

---

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

---

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

---

Temperature	99.0 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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 NOV 2020
------	-------------

---

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

---

O2 Saturation	94 %
---------------	------

---

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

---

Temperature	99.0 F
-------------	--------

---

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

---

Cough	None	<input 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 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	16 NOV 2020
------	-------------

---

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

---

O2 Saturation	83 %
---------------	------

---

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

---

Temperature	99.0 F
-------------	--------

---

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

---

Cough	None	<input 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 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	17 NOV 2020
------	-------------

---

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

---

O2 Saturation	92 %
---------------	------

---

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

---

Temperature	98.9 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 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	18 NOV 2020
------	-------------

---

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

---

O2 Saturation	94 %
---------------	------

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	19 NOV 2020
------	-------------

---

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

---

O2 Saturation	94 %
---------------	------

---

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

---

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

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	06 NOV 2020
------	-------------

---

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

---

O2 Saturation	ND - Not Done
---------------	---------------

---

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

---

Temperature	ND - Not Done
-------------	---------------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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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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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 13 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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"/>

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Form: Symptom Log (8)

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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 NOV 2020
------	-------------

---

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

---

O2 Saturation	ND - Not Done
---------------	---------------

---

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

---

Temperature	ND - Not Done
-------------	---------------

---

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

---

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

---

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

---

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

---

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EAB) (1725)

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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 (8)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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	08 NOV 2020
------	-------------

---

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

---

O2 Saturation	ND - Not Done
---------------	---------------

---

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

---

Temperature	ND - Not Done
-------------	---------------

---

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

---

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

---

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

---

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

---

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EAB) (1725)

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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 (9)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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 13 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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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Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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

---

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

---

O2 Saturation	ND - Not Done
---------------	---------------

---

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

---

Temperature	ND - Not Done
-------------	---------------

---

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

---

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

---

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

---

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

---

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Data signed: (b) (4) 26 Apr 2021 22:46:06

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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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Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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 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 (11)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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

---

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

---

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

---

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

---

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

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---

Not Done

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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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

US3402194

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Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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"/>

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	11 NOV 2020
------	-------------

---

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

---

O2 Saturation	ND - Not Done
---------------	---------------

---

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

---

Temperature	ND - Not Done
-------------	---------------

---

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

---

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

---

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

---

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

---

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Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input 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 (12)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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

---

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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	12 NOV 2020
------	-------------

---

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

---

O2 Saturation	ND - Not Done
---------------	---------------

---

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

---

Temperature	ND - Not Done
-------------	---------------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

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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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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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 13 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 (14)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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	13 NOV 2020
------	-------------

---

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

---

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

---

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

---

Temperature	99.3 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

---

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

---

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

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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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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	20 NOV 2020
------	-------------

---

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

---

O2 Saturation	94 %
---------------	------

---

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

---

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

---

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

---

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

---

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

---

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

---

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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 13 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	21 NOV 2020
------	-------------

---

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

---

O2 Saturation	94 %
---------------	------

---

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

---

Temperature	98.2 F
-------------	--------

---

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

---

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

---

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

---

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

---

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 type="checkbox"/>
Day 17	<input checked="" 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 (17)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	22 NOV 2020
------	-------------

---

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

---

O2 Saturation	92 %
---------------	------

---

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

---

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

---

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

---

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

---

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

---

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

---

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

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Generated On: 09 Jun 2021 17:27:28

---

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" 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 13 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	23 NOV 2020
------	-------------

---

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

---

O2 Saturation	92 %
---------------	------

---

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

---

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

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" 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 13 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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	24 NOV 2020
------	-------------

---

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

---

O2 Saturation	94 %
---------------	------

---

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

---

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

---

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

---

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

---

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

---

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

---

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

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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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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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 13 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" 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 (20)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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	25 NOV 2020
------	-------------

---

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

---

O2 Saturation	95 %
---------------	------

---

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

---

Temperature	98.2 F
-------------	--------

---

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

---

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

---

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

---

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

---

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---

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 (20)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 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 checked="" 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 (21)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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	26 NOV 2020
------	-------------

---

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

---

O2 Saturation	93 %
---------------	------

---

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

---

Temperature	98.2 F
-------------	--------

---

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

---

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

---

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

---

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

---

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---

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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Data signed: (b) (4) 26 Apr 2021 22:46:06

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Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 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 checked="" 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 (22)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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	27 NOV 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 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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Form: Symptom Log (22)

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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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Data signed: (b) (4) 26 Apr 2021 22:46:06

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Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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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Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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	28 NOV 2020
------	-------------

---

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

---

O2 Saturation	ND - Not Done
---------------	---------------

---

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

---

Temperature	ND - Not Done
-------------	---------------

---

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

---

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

---

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

---

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

---

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Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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 13 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 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 checked="" 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 (24)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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	29 NOV 2020
------	-------------

---

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

---

O2 Saturation	ND - Not Done
---------------	---------------

---

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

---

Temperature	ND - Not Done
-------------	---------------

---

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

---

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

---

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

---

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

---

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Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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 (24)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

Date	30 NOV 2020
------	-------------

---

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

---

O2 Saturation	95 %
---------------	------

---

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

---

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

---

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

---

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

---

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

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 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 checked="" 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 13 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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	1 DEC 2020
------	------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	90 %
---------------	------

---

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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	2 DEC 2020
------	------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	91 %
---------------	------

---

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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 3 DEC 2020

---

Assessment Not Done False

---

O2 Saturation 93 %

---

O2 Saturation Units %

---

Temperature 98.1 F

---

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

---

Cough

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

---

Shortness of Breath

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

---

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

---

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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 (28)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 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 checked="" 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 13 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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 4 DEC 2020

---

Assessment Not Done False

---

O2 Saturation 93 %

---

O2 Saturation Units %

---

Temperature 98.1 F

---

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

---

Cough

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

---

Shortness of Breath

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

---

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 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 checked="" type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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 5 DEC 2020

---

Assessment Not Done False

---

O2 Saturation 94 %

---

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 checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

---

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 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 checked="" type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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	6 DEC 2020
------	------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	94 %
---------------	------

---

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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 13 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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	7 DEC 2020
------	------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	100 %
---------------	-------

---

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	Day 33	<input checked="" type="radio"/>
	Day 34	<input type="radio"/>
	Day 35	<input type="radio"/>
	Day 36	<input type="radio"/>
	Day 37	<input type="radio"/>
	Day 38	<input type="radio"/>
	Day 39	<input type="radio"/>
	Day 40	<input type="radio"/>

---

Date	8 DEC 2020
------	------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	94 %
---------------	------

---

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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---

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

---

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

---

Nausea

None

Mild

Moderate

Severe

Not Done

---

Vomiting

None

Mild

Moderate

Severe

Not Done

---

Diarrhea

None

Mild

Moderate

Severe

Not Done

---

Sore Throat

None

Mild

Moderate

Severe

Not Done

---

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Form: Symptom Log (34)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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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Form: Symptom Log (34)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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---

	Day 33	<input type="checkbox"/>
	Day 34	<input checked="" 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 9 DEC 2020

---

Assessment Not Done False

---

O2 Saturation 98 %

---

O2 Saturation Units %

---

Temperature 98.1 F

---

Chills

None	<input checked="" type="checkbox"/>
Mild	<input 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 checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

---

Difficulty Breathing

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

---

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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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Data signed: (b) (4) 26 Apr 2021 22:46:06

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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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (35)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input checked="" 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 DEC 2020

---

Assessment Not Done False

---

O2 Saturation 94 %

---

O2 Saturation Units %

---

Temperature 97.2 F

---

Chills

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

---

Cough

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

---

Shortness of Breath

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

---

Difficulty Breathing

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

---

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Form: Symptom Log (35)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

US3402194

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Form: Symptom Log (35)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 13 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input checked="" type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date 11 DEC 2020

Assessment Not Done False

O2 Saturation 92 %

O2 Saturation Units %

Temperature 98.2 F

---

Chills	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

---

Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

---

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

---

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

---

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	Day 33	<input type="radio"/>
	Day 34	<input type="radio"/>
	Day 35	<input type="radio"/>
	Day 36	<input type="radio"/>
	Day 37	<input checked="" type="radio"/>
	Day 38	<input type="radio"/>
	Day 39	<input type="radio"/>
	Day 40	<input type="radio"/>

---

Date 12 DEC 2020

---

Assessment Not Done False

---

O2 Saturation 95 %

---

O2 Saturation Units %

---

Temperature 98.2 F

---

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

---

Cough

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

---

Shortness of Breath

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

---

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

---

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EAB) (1725)

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Form: Symptom Log (37)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

---

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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 checked="" type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date 13 DEC 2020

---

Assessment Not Done False

---

O2 Saturation 95 %

---

O2 Saturation Units %

---

Temperature 98.1 F

---

Chills

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

---

Cough

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

---

Shortness of Breath

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>
Not Done	<input type="checkbox"/>

---

Difficulty Breathing

None	<input checked="" type="checkbox"/>
Mild	<input type="checkbox"/>
Moderate	<input type="checkbox"/>
Severe	<input type="checkbox"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Data signed: (b) (4) 26 Apr 2021 22:46:06

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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



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

	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 checked="" type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	14 DEC 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	36.8 C
Chills	None <input checked="" type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>
Cough	None <input checked="" type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>
Shortness of Breath	None <input checked="" type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>
Difficulty Breathing	None <input checked="" type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

Date of Visit 13 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes   
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes   
No

Date of Test 13 NOV 2020

Type of Test Performed Nasopharyngeal Swab   
Nasal Swab   
Saliva Test   
Other

Other, specify \_\_\_\_\_

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes   
No

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes   
No

COVID-19 Positive (CSA Programming Field Only) 1

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 \_\_\_\_\_ 16 NOV 2020

End Date \_\_\_\_\_ 14 DEC 2020

Oxygen Saturation \_\_\_\_\_ 83 %

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 \_\_\_\_\_

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen? Yes  No

Start Date 16 OCT 2020

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



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

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 \_\_\_\_\_

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

[Generate Next COVID-19 Assessment](#)

Yes

No

---

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 22:46:07

Generated On: 09 Jun 2021 17:27:28

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 NOV 2020
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	Yes	14 DEC 2020

US3402194

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 13 NOV 2020

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID SICKD1

---

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	11:37 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 11:37
Height ( <i>xxx.x</i> )	ND - Not Done
Weight ( <i>xxx.x</i> )	ND - Not Done
Temperature ( <i>xxx.x</i> )	99.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	87 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3402194

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

13 NOV 2020

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3402194

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was Blood Sample Taken for Immunologic Assessment of SARS\_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

---

Date of Collection

13 NOV 2020

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 DEC 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

---



US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

Were vital signs assessed? Yes   
No

Date of assessment (*dd MMM yyyy*) 14 DEC 2020

Time of assessment (*00:00-23:59*) 13:06 (24 HR)

Vital Signs Date and Time (derived) 14 DEC 2020 13:06

Height (*xxx.x*) 160 cm

Weight (*xxx.x*) 99.7 kg

Temperature (*xxx.x*) 36.8 C

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (*xxx*) 81 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 15 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 120 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 79 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

14 DEC 2020

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Apr 2021 22:46:06

Generated On: 09 Jun 2021 17:27:28

---

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

---

Date of Collection

14 DEC 2020

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 4 FEB 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID UNBLND\_DECIDE

---

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

Date of updated informed consent ( <i>dd MMM yyyy</i> )	06 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> )	4 FEB 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 checked="" type="radio"/> Not Administered <input 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

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

---

---

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

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)	4 FEB 2021
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 15:20
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

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)	4 FEB 2021
Time of assessment (00:00-23:59)	16:06 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 16:06
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG



US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

4 FEB 2021

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

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) 4 FEB 2021

What was the treatment time? (00:00-23:59) 15:46 (24 HR)

Treatment Date and Time (derived) 4 FEB 2021 15:46

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

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	4 FEB 2021
Collection time ( <i>00:00-23:59</i> )	14:55 (24 HR)
Collection date and time (derived)	4 FEB 2021 14:55

---

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	4 FEB 2021
Collection time ( <i>00:00 - 23:59</i> )	14:50
Collection Date and Time (derived)	4 FEB 2021 14:50

---

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 FEB 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3402194

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

---

US3402194

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 2 MAR 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID OLD29

---



US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

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> )	2 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	12:11 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 12:11
Temperature ( <i>xxx.x</i> )	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	65 mmHg
Diastolic Blood Pressure units	MMHG

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

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> )	2 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	13:16 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 13:16
Temperature ( <i>xxx.x</i> )	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	73 mmHg
Diastolic Blood Pressure units	MMHG

US3402194

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

2 MAR 2021

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3402194

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

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) 2 MAR 2021

What was the treatment time? (00:00-23:59) 12:30 (24 HR)

Treatment Date and Time (derived) 2 MAR 2021 12:30

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

US3402194

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 MAR 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3402194

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:46:28

Generated On: 09 Jun 2021 17:27:28

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3402194

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 30 MAR 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID OLD57

---



US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

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) \_\_\_\_\_

US3402194

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

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.*

---

US3402194

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 30 MAR 2021

---

Collection time (*00:00-23:59*) 12:37 (24 HR)

---

Collection date and time (derived) 30 MAR 2021 12:37

---

US3402194

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:38:44

Generated On: 09 Jun 2021 17:27:28

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:38:44

Generated On: 09 Jun 2021 17:27:28

AEID	USA-US059-2020-MRNA-1273-P30 1000018
Adverse event	SARS 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)	06 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	26 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:38:44

Generated On: 09 Jun 2021 17:27:28

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	WHILE SUBJECT WAS DISCHARGED 26NOV2020 HE WAS SENT HOME WITH SUPPLEMENTAL OXYGEN OF 1 LITER TO USE AS NEEDED.
Narrative	

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:38:44

Generated On: 09 Jun 2021 17:27:28

---

SUBJECT PHONED OFFICE  
13NOV2020 THAT HE WAS  
HAVING COVID LIKE  
SYMPTOMS WHICH HAD  
STARTED 06NOV2020. AT THAT  
POINT HE HAD DIARRHEA,  
WHICH HE THOUGHT WAS A  
GASTROINTESTINAL ISSUE  
NOT COVID RELATED. UPON  
RECEIVING THE PHONE CALL A  
HOME VISIT WAS PREFORMED  
BY 2 COORDINATORS, AND THE  
PHYSICIAN SPOKE TO THE  
SUBJECT BY TELEPHONE.  
SUBJECT WAS FOLLOWED PER  
PROTOCOL  
FOR THE CONVALESCENT  
DAYS. SUBJECT PRESENTED TO  
THE EMERGENCY ROOM  
16NOV2020 WITH SHORTNESS  
OF BREATH. A CHEST X RAY  
WAS PERFORMED WHICH  
SHOWED BILATERAL AIR  
SPACE DISEASE CONCERNING  
FOR PNEUMONIA. SUBJECT  
ALSO HAD ELEVATED  
LACTATE OF 1181, D-DIMER 216,  
CRP 20.3, FERRITIN 912.  
SUBJECT WAS STARTED ON  
REMDESIVER, CONVALESCENT  
PLASMA, DEXAMETHASONE,  
THIAMINE, LOVENOX,  
OXYGEN, AND MELATONIN.  
ONCC SUBJECT WAS STARTED  
ON THE 6

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:38:44

Generated On: 09 Jun 2021 17:27:28

---

LITERS OF OXYGEN HE STATED  
FEELING MUCH BETTER AND  
THAT HIS SYMPTOMS WERE  
RESOLVING. SUBJECT  
COMPLETED A 5 DAY COURSE  
OF REMDESIVER, AND 10 DAYS  
OF DEXAMETHASONE. DUE  
TO SUBJECT NOT KEEPING A  
STABLE OXYGEN SATURATION  
HE WAS SENT HOME ON 1  
LITER OF OXYGEN.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:30:23

Generated On: 09 Jun 2021 17:27:28

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

---

**If Yes, please complete Prior/Concomitant Medication and Vaccination form.**

---

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication ADMELOG U-100

Prophylaxis Yes   
No

Indication TYPE 1 DIABETES

Dose per administration 100

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify UNITS

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

---

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 1979

---

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) 3

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication BRILINTA

Prophylaxis Yes   
No

Indication PERIPHERAL VASCULAR DISEASE

Dose per administration 90

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

---

	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 2018

---

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

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication ATORVASTATIN

Prophylaxis Yes   
No

Indication CORONARY ARTERY DISEASE

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN MAY 2017

---

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

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication LISINOPRIL

Prophylaxis Yes   
No

Indication CORONARY ARTERY DISEASE

Dose per administration 2.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) UN MAY 2017

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

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication ALBUTEROL

Prophylaxis Yes   
No

Indication SARS-COV-2

Dose per administration 90

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

- 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) 16 NOV 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication DEXAMETHASONE

Prophylaxis Yes   
No

Indication SARS-COV-2

Dose per administration 6

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

---

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 checked="" 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) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication ACETAMINOPHEN

Prophylaxis Yes   
No

Indication SARS-COV-2

Dose per administration 650

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

EVERY 4 HOURS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

---

	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

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication DEXTROSE (D50W SOLUTION)

Prophylaxis Yes   
No

Indication SARS-COV-2

Dose per administration 50

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" 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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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Name of Medication FUROSEMIDE

Prophylaxis Yes   
No

Indication FLUID RETENSION DUE TO SARS-COV-2

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

---

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify	
Start date (dd MMM yyyy)	16 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 NOV 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication ASCORBIC ACID

Prophylaxis Yes   
No

Indication SARS-COV-2

Dose per administration 1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

---

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 checked="" 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*) 17 NOV 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 3

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication SARS-COV-2

Dose per administration 81

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

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*) 26 NOV 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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Name of Medication GLUCOSE CHEWABLE TABLET

Prophylaxis Yes   
No

Indication TYPE 2 DIABETIS WITH  
SARS-COV-2

Dose per administration 4

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 (12)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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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) 16 NOV 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) 26 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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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Name of Medication HEPARIN

Prophylaxis Yes   
No

Indication SARS-COV-2

Dose per administration 40

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify UNITS/KG

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 (13)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date ( <i>dd MMM yyyy</i> )	16 NOV 2020
-----------------------------------	-------------

---

Start date completely unknown	False
-------------------------------	-------

---

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

If not Ongoing, End date ( <i>dd MMM yyyy</i> )	17 NOV 2020
---	-------------

---

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

Separate Dosage Number (derived)	4
----------------------------------	---

---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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Name of Medication D5W

Prophylaxis Yes   
No

Indication FLUID LOSS DUE TO SARS-COV-2

Dose per administration 0-24

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify UNITS/KG/HOUR

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 (14)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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---

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 checked="" 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)	16 NOV 2020
--------------------------	-------------

---

Start date completely unknown	False
-------------------------------	-------

---

Ongoing?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

---

If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020
--	-------------

---

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

---

Separate Dosage Number (derived)	4
----------------------------------	---

---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

---

Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication INSULIN GLARGINE

Prophylaxis Yes   
No

Indication DIABETES TYPE 1

Dose per administration 30

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify UNITS

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 (15)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 16 NOV 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) 3

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication INSULIN LISPRO

Prophylaxis Yes   
No

Indication DIABETES TYPE 1

Dose per administration 2-6

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify UNITS

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 (16)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 16 NOV 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) 3

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

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Name of Medication REMDESIVIR

Prophylaxis Yes   
No

Indication SARS-COV-2

Dose per administration 100

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

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---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date ( <i>dd MMM yyyy</i> )	18 NOV 2020
-----------------------------------	-------------

---

Start date completely unknown	False
-------------------------------	-------

---

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

If not Ongoing, End date ( <i>dd MMM yyyy</i> )	18 NOV 2020
---	-------------

---

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

Separate Dosage Number (derived)	1
----------------------------------	---

---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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Name of Medication SODIUM CHLORIDE INFUSION

Prophylaxis Yes   
No

Indication SARS-COV-2

Dose per administration 0.9

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 (18)

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- 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*) 16 NOV 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 26 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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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Name of Medication THIAMINE

Prophylaxis Yes   
No

Indication SARS-COV-2

Dose per administration 100

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" 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*) 17 NOV 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 26 NOV 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 23:30:19

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Name of Medication OXYGEN

Prophylaxis Yes   
No

Indication SARS COVID 19

Dose per administration 6

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify LITERS

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 CONTINUOUS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

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- 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) 16 NOV 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 26 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

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

Name of Medication LOVENOX

Prophylaxis Yes   
No

Indication SARS COVID-19

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify MG/KG

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)

557 of 3478

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 23:30:19

Generated On: 09 Jun 2021 17:27:28

---

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*) 17 NOV 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 26 NOV 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3402194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:30:23

Generated On: 09 Jun 2021 17:27:28

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3402194

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:27:28

---

Date of dosing discontinuation (dd MMM yyyy)

---

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

---

US3402194

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:27:28

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

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

SAEID	USA-US059-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

SAEID	USA-US059-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/NOV/2020 15:54
<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



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

SAEID	USA-US059-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/NOV/2020 15:03
<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>	<input checked="" type="checkbox"/> True

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

SAEID	USA-US059-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/NOV/2020 15:25
<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

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

SAEID	USA-US059-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/DEC/2020 12:41
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	True

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 22:46:08

Generated On: 09 Jun 2021 17:27:28

SAEID	USA-US059-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/DEC/2020 08:35
<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

US3402194 (Prod: Meridian Clinical Research, LLC)

**US3402194**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:27:28**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'US3402194'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 20:19:12

US3402194

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:32:14

US3402194

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '02 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 20:19:13



US3402194

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:14

**US3402194**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'SCRN'	System	03 Aug 2020 14:32:14

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 20:19:14

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '57'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'YEARS'	System	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered '58'	System	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Male (M)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:32:41



US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '1'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41



US3402194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:28

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:32:41

US3402194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:28

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:28

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'Aug 2020'	System	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:28

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered '2020'	System	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:28

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Amendment 1 (1)'	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:28

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:28

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:07
	(b) (4)	

US3402194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:07
	(b) (4)	



US3402194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:07

US3402194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 20:19:13

US3402194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:28

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered '1'	System	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:27:28

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:27:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:29

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type 1 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 17:57:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 17:57:04
Data point term sent to Coder	System	03 Aug 2020 14:34:18
User entered 'type 1 diabetes'	Traci Hull (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'un UNK 1979'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:49



US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'Jan 1979'	System	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered '1979'	System	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:28

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered empty.	System	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:28

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered empty.	System	03 Aug 2020 14:33:49

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Peripheral vascular disorder, LLT: Peripheral vascular disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 14:35:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 14:35:06
Data point term sent to Coder	System	03 Aug 2020 14:34:18
User entered 'peripheral vascular disease'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:06



US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'un UNK 2018'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:28

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'Jan 2018'	System	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered '2018'	System	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:28

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered empty.	System	03 Aug 2020 14:34:06



US3402194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:28

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered empty.	System	03 Aug 2020 14:34:06

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	03 Aug 2020 14:36:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 14:36:00
Data point term sent to Coder	System	03 Aug 2020 14:35:18
User entered 'coronary artery disease'	Traci Hull (b) (4)	03 Aug 2020 14:34:33
	(b) (4)	

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'un May 2017'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:28

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'May 2017'	System	03 Aug 2020 14:34:33



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered '2017'	System	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:28

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered empty.	System	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:28

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered empty.	System	03 Aug 2020 14:34:33

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Aug 2020'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '16:15'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:37:39

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered '2 Aug 2020 16:15'	System	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '160' cm	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:37:39
DataPoint set to visible.	(b) (4) System	02 Aug 2020 20:57:11



US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '99.7' kg	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:37:39
DataPoint set to visible.	(b) (4) System	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
Amendment Manager: User entered '38.94531'	System	16 Sep 2020 23:40:49
User entered '38.9'	System	03 Aug 2020 14:37:39
DataPoint set to visible.	System	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'kg/m2'	System	03 Aug 2020 14:37:39
DataPoint set to visible.	System	02 Aug 2020 20:57:11

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User closed query 'Per CDM re-query: For Screening and Visit 1 on the same day, to avoid duplication of data, TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP should be recorded as 'ND-NOT DONE'. Please remove the data and enter 'ND - NOT DONE' in the data field of EDC. Thank you	(b) (4) (b) (4), (b) (6)	12 Oct 2020 09:45:01
' (Site from DM). Query 'Per CDM re-query: For Screening and Visit 1 on the same day, to avoid duplication of data, TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP should be recorded as 'ND-NOT DONE'. Please remove the data and enter 'ND - NOT DONE' in the data field of EDC. Thank you	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 14:48:47
' answered with 'NOT DONE' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 14:48:41
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:16:56
User opened query 'Per CDM re-query: For Screening and Visit 1 on the same day, to avoid duplication of data, TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP should be recorded as 'ND-NOT DONE'. Please remove the data and enter 'ND - NOT DONE' in the data field of EDC. Thank you	(b) (4), (b) (6)	09 Oct 2020 12:16:48
' (Site from DM).		

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4) (b) (4)	08 Oct 2020 14:35:53
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:49:05
User entered '37.0' C	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
	(b) (4)	
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 14:48:41
	(b) (4)	
User entered 'Oral (Oral)'	Traci Hull (b) (4)	03 Aug 2020 14:37:39
	(b) (4)	

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	09 Oct 2020 14:48:41
	(b) (4)	
User entered '78'	Traci Hull (b) (4)	03 Aug 2020 14:37:39
	(b) (4)	



US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'bpm'	System	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 14:48:41
User entered '14'	Tammy Kohn (b) (4)	09 Oct 2020 14:48:41
	(b) (4)	
	Traci Hull (b) (4)	03 Aug 2020 14:37:39
	(b) (4)	

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'breaths/min'	System	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 14:48:41
User entered '104'	Tammy Kohn (b) (4)	09 Oct 2020 14:48:41
	(b) (4)	
	Traci Hull (b) (4)	03 Aug 2020 14:37:39
	(b) (4)	

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'mmHg'	System	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 14:48:41
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 17:49:38
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS IS. NOT CLINICALLY SIGNIFICANT' (Site from System).	Traci Hull (b) (4) (b) (4)	22 Sep 2020 20:03:12
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:40:49
User entered '56'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User entered 'mmHg'	System	03 Aug 2020 14:37:39

US3402194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55



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Folder: Screening

Form: Vital Signs

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[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55

US3402194

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:38:01

US3402194

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 12:33:30
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 12:27:49
User entered '2 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:01

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Folder: Screening

Form: Risk of Exposure

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Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

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[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18



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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

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[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)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

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[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)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

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**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'none'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18



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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:28

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:28

**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)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:28

[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)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

US3402194

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:28

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)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:28

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '1'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:33:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:35:55
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:33:18



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:38:17

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Aug 2020'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:38:17

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:38:17

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'VISIT1'	System	03 Aug 2020 14:38:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:28

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '02 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 20:19:18

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:28

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:41:18
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:41:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Aug 2020 20:19:18
User entered '142630' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 20:19:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:28

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 20:19:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:28

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)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:38:31



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Folder: Visit 1 Day 1

Form: Randomization

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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)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:38:31

US3402194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:28

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:38:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:28

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:38:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:28

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:38:31

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User closed query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:21:35
Query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' answered with 'DATA UPDATED NOT DONE ND' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	13 Oct 2020 18:26:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	13 Oct 2020 18:26:40
User opened query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:39:32
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:39:32
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4) (b) (4)	08 Oct 2020 14:35:34
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:49:24
User entered '160' cm	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 18:26:40
User entered '99.7' kg	Tammy Kohn (b) (4)	13 Oct 2020 18:26:40
	(b) (4)	
	Traci Hull (b) (4)	03 Aug 2020 14:40:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User closed query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:21:35
Query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' answered with 'DATA UPDATED NOT DONE ND' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	13 Oct 2020 18:26:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	13 Oct 2020 18:26:40
User opened query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:39:32
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:39:32
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4) (b) (4)	08 Oct 2020 14:35:34
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:49:24
User entered '160' cm	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 18:26:40
User entered '99.7' kg	Tammy Kohn (b) (4)	13 Oct 2020 18:26:40
	(b) (4)	
	Traci Hull (b) (4)	03 Aug 2020 14:40:19
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Aug 2020'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '16:15'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '2 Aug 2020 16:15'	System	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
	(b) (4)	
User entered '37.0' C	Traci Hull (b) (4)	03 Aug 2020 14:40:19
	(b) (4)	

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19
	(b) (4)	

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '78'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'bpm'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '14'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'breaths/min'	System	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '104'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'mmHg'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User closed query 'Per CDM: Per previous query, please confirm if this result should be considered Clinically Significant or not.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:49:14
Query 'Per CDM: Per previous query, please confirm if this result should be considered Clinically Significant or not.' answered with 'CORRECT AS IS. NOT CLINICALLY SIGNIFICANT' (Site from DM).	Traci Hull (b) (4) (b) (4)	22 Sep 2020 20:02:15
User opened query 'Per CDM: Per previous query, please confirm if this result should be considered Clinically Significant or not.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:53:52
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 14:53:08
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'correct as is' (Site from System).	Traci Hull (b) (4) (b) (4)	18 Sep 2020 12:34:09
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:40:49
User entered '56'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'mmHg'	System	03 Aug 2020 14:40:19



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User closed query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:21:35
Query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' answered with 'DATA UPDATED NOT DONE ND' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	13 Oct 2020 18:26:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	13 Oct 2020 18:26:40
User opened query 'Per CDM re-query: Per previous query, height and weight are already recorded at Screening. To avoid duplication of data, please delete entries for height and weight on this page and record them as 'Not Done'.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:39:32
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:39:32
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4) (b) (4)	08 Oct 2020 14:35:34
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:49:24
User entered '160' cm	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Oct 2020 18:26:40
User entered '99.7' kg	Tammy Kohn (b) (4)	13 Oct 2020 18:26:40
	(b) (4)	
	Traci Hull (b) (4)	03 Aug 2020 14:40:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Aug 2020'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
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)	17 Aug 2020 14:02:50
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 minutes' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:29
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).		03 Aug 2020 14:40:19
User entered '17:27'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '2 Aug 2020 17:27'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
	(b) (4)	
User entered '36.7' C	Traci Hull (b) (4)	03 Aug 2020 14:40:19
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '73'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'bpm'	System	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '12'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'breaths/min'	System	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '120'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'mmHg'	System	03 Aug 2020 14:40:19



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '65'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'mmHg'	System	03 Aug 2020 14:40:19

US3402194

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:40

**US3402194**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:28**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Aug 2020'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:40:40

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:32
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

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)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:32
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'MRNA-1273 OR PLACEBO'	System	02 Aug 2020 20:57:32



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:32

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '16:48'	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:32

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '2 Aug 2020 16:48'	System	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tarin Gordon (b) (4)	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'ONCE'	System	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'INTRAMUSCULAR'	System	02 Aug 2020 20:57:32

US3402194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:41:01

US3402194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under Visit 1 Day 1 Visit with date 03AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 06:30:18
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under Visit 1 Day 1 Visit with date 03AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'DATA WAS UPDATED BY THE LAB.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 12:17:21
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under Visit 1 Day 1 Visit with date 03AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:02:03
User entered '2 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:01



US3402194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '16:25'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:01

**US3402194**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '2 Aug 2020 16:25'	System	03 Aug 2020 14:41:01

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:27:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:28:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:28:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:28:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:28:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '16:28'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:28:42
Query 'Per GCL Lab Reconciliation: Swab: The collection date of Visit 2 Day 29 in EDC is entered as 02AUG2020. However, collection date in GCL for the same visit is recorded as 03AUG2020. Please review and confirm the correct collection date. Thank you' canceled (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:58:43
User opened query 'Per GCL Lab Reconciliation: Swab: The collection date of Visit 2 Day 29 in EDC is entered as 02AUG2020. However, collection date in GCL for the same visit is recorded as 03AUG2020. Please review and confirm the correct collection date. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:15:18
User entered '2 Aug 2020 16:28'	System	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:28:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33



US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:28:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:28:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:28:42
User entered empty.	System	03 Aug 2020 14:41:33

US3402194

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 14:41:55

US3402194

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '1'	System	03 Aug 2020 14:41:55

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:11', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c579a454-de27-44d5-8028-e54a57943564' User entered 'Yes (Y)'	System	02 Aug 2020 21:27:40
	System	02 Aug 2020 21:27:40

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c579a454-de27-44d5-8028-e54a57943564' User entered '98.1'	System	02 Aug 2020 21:27:40
	System	02 Aug 2020 21:27:40



US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c579a454-de27-44d5-8028-e54a57943564'	System	02 Aug 2020 21:27:40
User entered 'No (N)'	System	02 Aug 2020 21:27:40

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:30', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c579a454-de27-44d5-8028-e54a57943564' User entered '02 Aug 2020 17:27'	System	02 Aug 2020 21:27:40
	System	02 Aug 2020 21:27:40

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Aug 2020 17:08'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Aug 2020 19:38'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:44:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f3dbd53a-f194-4c7d-a0a4-cebd5185b2e9' User entered 'Yes (Y)'	System	03 Aug 2020 02:45:35
	System	03 Aug 2020 02:45:35

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:45:05', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f3dbd53a-f194-4c7d-a0a4-cebd5185b2e9' User entered '98.1'	System	03 Aug 2020 02:45:35
	System	03 Aug 2020 02:45:35

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:45:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f3dbd53a-f194-4c7d-a0a4-cebd5185b2e9' User entered 'No (N)'	System	03 Aug 2020 02:45:35
	System	03 Aug 2020 02:45:35



US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:45:33', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f3dbd53a-f194-4c7d-a0a4-cebd5185b2e9' User entered '02 Aug 2020 22:45'	System	03 Aug 2020 02:45:35
	System	03 Aug 2020 02:45:35

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Aug 2020 20:33'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 2'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:14:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ca650b6f-1039-41af-8314-400f5163f0db' User entered 'Yes (Y)'	System	04 Aug 2020 13:14:53
	System	04 Aug 2020 13:14:53

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:14:38', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ca650b6f-1039-41af-8314-400f5163f0db' User entered '98.1'	System	04 Aug 2020 13:14:53
	System	04 Aug 2020 13:14:53

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:14:45', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ca650b6f-1039-41af-8314-400f5163f0db' User entered 'No (N)'	System	04 Aug 2020 13:14:53
	System	04 Aug 2020 13:14:53

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:14:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ca650b6f-1039-41af-8314-400f5163f0db' User entered '04 Aug 2020 09:14'	System	04 Aug 2020 13:14:53
	System	04 Aug 2020 13:14:53



US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 3'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:21', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '99733174-b331-43bf-8cac-f18e3c8fcf03'	System	04 Aug 2020 16:10:42
User entered 'Yes (Y)'	System	04 Aug 2020 16:10:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:30', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '99733174-b331-43bf-8cac-f18e3c8fcf03' User entered '98.1'	System	04 Aug 2020 16:10:42
	System	04 Aug 2020 16:10:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '99733174-b331-43bf-8cac-f18e3c8fcf03'	System	04 Aug 2020 16:10:42
User entered 'No (N)'	System	04 Aug 2020 16:10:42

**US3402194**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:27:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '99733174-b331-43bf-8cac-f18e3c8fcf03'	System	04 Aug 2020 16:10:42
User entered '04 Aug 2020 12:10'	System	04 Aug 2020 16:10:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 4'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:15', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ef308d3c-5672-4ee5-b374-1f02b1b7dd3d' User entered 'Yes (Y)'	System	05 Aug 2020 16:00:26
	System	05 Aug 2020 16:00:26

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ef308d3c-5672-4ee5-b374-1f02b1b7dd3d' User entered '98.1'	System	05 Aug 2020 16:00:26
	System	05 Aug 2020 16:00:26

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ef308d3c-5672-4ee5-b374-1f02b1b7dd3d' User entered 'No (N)'	System	05 Aug 2020 16:00:26
	System	05 Aug 2020 16:00:26

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ef308d3c-5672-4ee5-b374-1f02b1b7dd3d' User entered '05 Aug 2020 12:00'	System	05 Aug 2020 16:00:26
	System	05 Aug 2020 16:00:26

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 5'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 6'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e6d62809-0376-4bb0-97ac-965020c39e1b' User entered 'Yes (Y)'	System	07 Aug 2020 16:12:42
	System	07 Aug 2020 16:12:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:34', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e6d62809-0376-4bb0-97ac-965020c39e1b' User entered '98.1'	System	07 Aug 2020 16:12:42
	System	07 Aug 2020 16:12:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e6d62809-0376-4bb0-97ac-965020c39e1b' User entered 'No (N)'	System	07 Aug 2020 16:12:42
	System	07 Aug 2020 16:12:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:39', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e6d62809-0376-4bb0-97ac-965020c39e1b' User entered '07 Aug 2020 12:12'	System	07 Aug 2020 16:12:42
	System	07 Aug 2020 16:12:42

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 7'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:51:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '67a70979-98b4-4d2e-8b20-f933fb7a4abb' User entered 'Yes (Y)'	System	08 Aug 2020 16:52:05
	System	08 Aug 2020 16:52:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:51:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '67a70979-98b4-4d2e-8b20-f933fb7a4abb' User entered '98.1'	System	08 Aug 2020 16:52:05
	System	08 Aug 2020 16:52:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:51:57', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '67a70979-98b4-4d2e-8b20-f933fb7a4abb'	System	08 Aug 2020 16:52:05
User entered 'No (N)'	System	08 Aug 2020 16:52:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '67a70979-98b4-4d2e-8b20-f933fb7a4abb' User entered '08 Aug 2020 12:52'	System	08 Aug 2020 16:52:05
	System	08 Aug 2020 16:52:05

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:42', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '46360fd2-232a-4efc-b89c-5b64e9c80f65'	System	02 Aug 2020 21:28:05
User entered 'None (1)'	System	02 Aug 2020 21:28:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '46360fd2-232a-4efc-b89c-5b64e9c80f65'	System	02 Aug 2020 21:28:05
User entered 'No (N)'	System	02 Aug 2020 21:28:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '46360fd2-232a-4efc-b89c-5b64e9c80f65'	System	02 Aug 2020 21:28:05
User entered 'No (N)'	System	02 Aug 2020 21:28:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:27:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '46360fd2-232a-4efc-b89c-5b64e9c80f65'	System	02 Aug 2020 21:28:05
User entered 'None (1)'	System	02 Aug 2020 21:28:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:02', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '46360fd2-232a-4efc-b89c-5b64e9c80f65' User entered '02 Aug 2020 17:28'	System	02 Aug 2020 21:28:05
	System	02 Aug 2020 21:28:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Aug 2020 17:08'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Aug 2020 19:38'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:45:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c775aa9d-aac8-4b7e-93c1-17f21225478e' User entered 'None (1)'	System	03 Aug 2020 02:46:24
	System	03 Aug 2020 02:46:24

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:45:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c775aa9d-aac8-4b7e-93c1-17f21225478e' User entered 'No (N)'	System	03 Aug 2020 02:46:24
	System	03 Aug 2020 02:46:24

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:05', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c775aa9d-aac8-4b7e-93c1-17f21225478e' User entered 'No (N)'	System	03 Aug 2020 02:46:24
	System	03 Aug 2020 02:46:24

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c775aa9d-aac8-4b7e-93c1-17f21225478e' User entered 'None (1)'	System	03 Aug 2020 02:46:24
	System	03 Aug 2020 02:46:24

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c775aa9d-aac8-4b7e-93c1-17f21225478e' User entered '02 Aug 2020 22:46'	System	03 Aug 2020 02:46:24
	System	03 Aug 2020 02:46:24

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Aug 2020 20:33'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 2'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '65745532-3c6d-4c4e-b44f-1d89bdfacc8'	System	04 Aug 2020 13:15:33
User entered 'None (1)'	System	04 Aug 2020 13:15:33

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '65745532-3c6d-4c4e-b44f-1d89bdfacc8'	System	04 Aug 2020 13:15:33
User entered 'No (N)'	System	04 Aug 2020 13:15:33

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '65745532-3c6d-4c4e-b44f-1d89bfdfac8'	System	04 Aug 2020 13:15:33
User entered 'No (N)'	System	04 Aug 2020 13:15:33

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '65745532-3c6d-4c4e-b44f-1d89bdfacc8'	System	04 Aug 2020 13:15:33
User entered 'None (1)'	System	04 Aug 2020 13:15:33

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:30', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '65745532-3c6d-4c4e-b44f-1d89bdfacc8' User entered '04 Aug 2020 09:15'	System	04 Aug 2020 13:15:33
	System	04 Aug 2020 13:15:33

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 3'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:51', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2ac7dc31-b59f-46ee-bcc1-1193ecb5de54'	System	04 Aug 2020 16:11:04
User entered 'None (1)'	System	04 Aug 2020 16:11:04

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2ac7dc31-b59f-46ee-bcc1-1193ecb5de54'	System	04 Aug 2020 16:11:04
User entered 'No (N)'	System	04 Aug 2020 16:11:04

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:57', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2ac7dc31-b59f-46ee-bcc1-1193ecb5de54' User entered 'No (N)'	System	04 Aug 2020 16:11:04
	System	04 Aug 2020 16:11:04

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:10:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2ac7dc31-b59f-46ee-bcc1-1193ecb5de54'	System	04 Aug 2020 16:11:04
User entered 'None (1)'	System	04 Aug 2020 16:11:04

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2ac7dc31-b59f-46ee-bcc1-1193ecb5de54' User entered '04 Aug 2020 12:11'	System	04 Aug 2020 16:11:04
	System	04 Aug 2020 16:11:04

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 4'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:30', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '6a68122a-27da-43eb-8b7e-4b8cdb255834'	System	05 Aug 2020 16:00:42
User entered 'None (1)'	System	05 Aug 2020 16:00:42

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:32', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '6a68122a-27da-43eb-8b7e-4b8cdb255834' User entered 'No (N)'	System	05 Aug 2020 16:00:42
	System	05 Aug 2020 16:00:42

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:34', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '6a68122a-27da-43eb-8b7e-4b8cdb255834' User entered 'No (N)'	System	05 Aug 2020 16:00:42
	System	05 Aug 2020 16:00:42

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:38', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '6a68122a-27da-43eb-8b7e-4b8cdb255834' User entered 'None (1)'	System	05 Aug 2020 16:00:42
	System	05 Aug 2020 16:00:42

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '6a68122a-27da-43eb-8b7e-4b8cdb255834' User entered '05 Aug 2020 12:00'	System	05 Aug 2020 16:00:42
	System	05 Aug 2020 16:00:42

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 5'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 6'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:49', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e1986a1a-e32d-4470-9e34-c0d6b735ba24' User entered 'None (1)'	System	07 Aug 2020 16:13:02
	System	07 Aug 2020 16:13:02

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e1986a1a-e32d-4470-9e34-c0d6b735ba24' User entered 'No (N)'	System	07 Aug 2020 16:13:02
	System	07 Aug 2020 16:13:02

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e1986a1a-e32d-4470-9e34-c0d6b735ba24' User entered 'No (N)'	System	07 Aug 2020 16:13:02
	System	07 Aug 2020 16:13:02

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:57', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e1986a1a-e32d-4470-9e34-c0d6b735ba24' User entered 'None (1)'	System	07 Aug 2020 16:13:02
	System	07 Aug 2020 16:13:02

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:12:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e1986a1a-e32d-4470-9e34-c0d6b735ba24' User entered '07 Aug 2020 12:12'	System	07 Aug 2020 16:13:02
	System	07 Aug 2020 16:13:02

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 7'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:05', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '742f6e79-0df4-4333-9ec6-f21f2a529cce' User entered 'None (1)'	System	08 Aug 2020 16:52:16
	System	08 Aug 2020 16:52:16

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '742f6e79-0df4-4333-9ec6-f21f2a529cce' User entered 'No (N)'	System	08 Aug 2020 16:52:16
	System	08 Aug 2020 16:52:16

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '742f6e79-0df4-4333-9ec6-f21f2a529cce' User entered 'No (N)'	System	08 Aug 2020 16:52:16
	System	08 Aug 2020 16:52:16

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:12', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '742f6e79-0df4-4333-9ec6-f21f2a529cce'	System	08 Aug 2020 16:52:16
User entered 'None (1)'	System	08 Aug 2020 16:52:16

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '742f6e79-0df4-4333-9ec6-f21f2a529cce' User entered '08 Aug 2020 12:52'	System	08 Aug 2020 16:52:16
	System	08 Aug 2020 16:52:16

US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5' User entered 'None (0)'	System	02 Aug 2020 21:28:35
	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5' User entered 'None (0)'	System	02 Aug 2020 21:28:35
	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5'	System	02 Aug 2020 21:28:35
User entered 'None (0)'	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5' User entered 'None (0)'	System	02 Aug 2020 21:28:35
	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5' User entered 'None (0)'	System	02 Aug 2020 21:28:35
	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5' User entered 'None (0)'	System	02 Aug 2020 21:28:35
	System	02 Aug 2020 21:28:35



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5' User entered 'No (N)'	System	02 Aug 2020 21:28:35
	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T17:28:32', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '39c139b7-7844-432e-8ff6-863ce077b1b5' User entered '02 Aug 2020 17:28'	System	02 Aug 2020 21:28:35
	System	02 Aug 2020 21:28:35

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Aug 2020 17:08'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Aug 2020 19:38'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:32', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d' User entered 'None (0)'	System	03 Aug 2020 02:47:16
	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:36', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d' User entered 'None (0)'	System	03 Aug 2020 02:47:16
	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:39', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d' User entered 'None (0)'	System	03 Aug 2020 02:47:16
	System	03 Aug 2020 02:47:16



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d' User entered 'None (0)'	System	03 Aug 2020 02:47:16
	System	03 Aug 2020 02:47:16

**US3402194**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:28**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:46:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d' User entered 'None (0)'	System	03 Aug 2020 02:47:16
	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:47:02', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d' User entered 'None (0)'	System	03 Aug 2020 02:47:16
	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:47:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d' User entered 'No (N)'	System	03 Aug 2020 02:47:16
	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-02T22:47:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ed1a2803-4633-4214-b9c3-7fed5cf93c6d' User entered '02 Aug 2020 22:47'	System	03 Aug 2020 02:47:16
	System	03 Aug 2020 02:47:16

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Aug 2020 20:33'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 2'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7' User entered 'None (0)'	System	04 Aug 2020 13:16:14
	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:45', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7' User entered 'None (0)'	System	04 Aug 2020 13:16:14
	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7' User entered 'None (0)'	System	04 Aug 2020 13:16:14
	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7' User entered 'None (0)'	System	04 Aug 2020 13:16:14
	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:15:57', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7' User entered 'None (0)'	System	04 Aug 2020 13:16:14
	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:16:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7' User entered 'None (0)'	System	04 Aug 2020 13:16:14
	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:16:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7' User entered 'No (N)'	System	04 Aug 2020 13:16:14
	System	04 Aug 2020 13:16:14

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T09:16:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '280a6c06-f25f-4aa8-a3d2-2d0d231e2de7' User entered '04 Aug 2020 09:16'	System	04 Aug 2020 13:16:14
	System	04 Aug 2020 13:16:14



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 3'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:06', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84' User entered 'None (0)'	System	04 Aug 2020 16:11:29
	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:09', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84' User entered 'None (0)'	System	04 Aug 2020 16:11:29
	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:11', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84'	System	04 Aug 2020 16:11:29
User entered 'None (0)'	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84' User entered 'None (0)'	System	04 Aug 2020 16:11:29
	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84' User entered 'None (0)'	System	04 Aug 2020 16:11:29
	System	04 Aug 2020 16:11:29



**US3402194**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:27:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84' User entered 'None (0)'	System	04 Aug 2020 16:11:29
	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84' User entered 'No (N)'	System	04 Aug 2020 16:11:29
	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-04T12:11:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '16b7353c-2571-4327-9003-62c1adc4ef84' User entered '04 Aug 2020 12:11'	System	04 Aug 2020 16:11:29
	System	04 Aug 2020 16:11:29

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 4'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered 'None (0)'	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered 'None (0)'	System	05 Aug 2020 16:01:02



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13' User entered 'None (0)'	System	05 Aug 2020 16:01:02
	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13' User entered 'None (0)'	System	05 Aug 2020 16:01:02
	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13' User entered 'None (0)'	System	05 Aug 2020 16:01:02
	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:55', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13' User entered 'None (0)'	System	05 Aug 2020 16:01:02
	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:00:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13'	System	05 Aug 2020 16:01:02
User entered 'No (N)'	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-05T12:01:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '68359bb7-7512-4ce3-b184-2aae3c724b13' User entered '05 Aug 2020 12:01'	System	05 Aug 2020 16:01:02
	System	05 Aug 2020 16:01:02

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 20:57:32



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 5'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 6'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:03', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23' User entered 'None (0)'	System	07 Aug 2020 16:13:25
	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:05', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23' User entered 'None (0)'	System	07 Aug 2020 16:13:25
	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:07', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23' User entered 'None (0)'	System	07 Aug 2020 16:13:25
	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23' User entered 'None (0)'	System	07 Aug 2020 16:13:25
	System	07 Aug 2020 16:13:25



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23' User entered 'None (0)'	System	07 Aug 2020 16:13:25
	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:12', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23' User entered 'None (0)'	System	07 Aug 2020 16:13:25
	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23'	System	07 Aug 2020 16:13:25
User entered 'No (N)'	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-07T12:13:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '514af771-c625-4b3d-ba51-efa9fb5d1c23'	System	07 Aug 2020 16:13:25
User entered '07 Aug 2020 12:13'	System	07 Aug 2020 16:13:25

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 7'	System	02 Aug 2020 20:57:32

**US3402194**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:27:28**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:18', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af' User entered 'None (0)'	System	08 Aug 2020 16:52:46
	System	08 Aug 2020 16:52:46



US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:21', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af' User entered 'None (0)'	System	08 Aug 2020 16:52:46
	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af' User entered 'None (0)'	System	08 Aug 2020 16:52:46
	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af' User entered 'None (0)'	System	08 Aug 2020 16:52:46
	System	08 Aug 2020 16:52:46

**US3402194**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:27:28**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:26', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af' User entered 'None (0)'	System	08 Aug 2020 16:52:46
	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:28', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af' User entered 'None (0)'	System	08 Aug 2020 16:52:46
	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:35', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af' User entered 'No (N)'	System	08 Aug 2020 16:52:46
	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-08-08T12:52:42', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e8488040-74d0-4d6a-8a40-3efd011925af' User entered '08 Aug 2020 12:52'	System	08 Aug 2020 16:52:46
	System	08 Aug 2020 16:52:46

US3402194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 20:57:32



**US3402194**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:27:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 17:41:53

US3402194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '9 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 17:41:53

US3402194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 17:41:53

US3402194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 17:41:53

US3402194

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 17:41:59

US3402194

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'I'	System	10 Aug 2020 17:41:59

US3402194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	17 Aug 2020 15:24:08



US3402194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '16 Aug 2020'	(b) (4) Traci Hull (b) (4)	17 Aug 2020 15:24:08
	(b) (4)	

US3402194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	17 Aug 2020 15:24:08

US3402194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	17 Aug 2020 15:24:08

US3402194

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	17 Aug 2020 15:24:14

**US3402194**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'I'	System	17 Aug 2020 15:24:14

US3402194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Jennifer Molstead (b) (4)	24 Aug 2020 18:24:45

US3402194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '23 Aug 2020'	(b) (4) Jennifer Molstead (b) (4)	24 Aug 2020 18:24:45
	(b) (4)	

US3402194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Molstead (b) (4)	24 Aug 2020 18:24:45



US3402194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	24 Aug 2020 18:24:45
	(b) (4)	

US3402194

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Jennifer Molstead (b) (4)	24 Aug 2020 18:24:54

US3402194

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '1'	System	24 Aug 2020 18:24:54

US3402194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:27:49

US3402194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Sep 2020'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:27:49
	(b) (4)	

US3402194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:27:49

US3402194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'VISIT2'	System	03 Sep 2020 12:27:49

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58



US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Sep 2020'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '15:07'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '2 Sep 2020 15:07'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
	(b) (4)	
User entered '37.1' C	Traci Hull (b) (4)	03 Sep 2020 12:28:58
	(b) (4)	

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58
	(b) (4)	

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '88'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58



US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'bpm'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '18'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'breaths/min'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '128'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'mmHg'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '72'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'mmHg'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58



US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Sep 2020'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '16:32'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '2 Sep 2020 16:32'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
	(b) (4)	
User entered '37.0' C	Traci Hull (b) (4)	03 Sep 2020 12:28:58
	(b) (4)	

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58
	(b) (4)	

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '96'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58



US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'bpm'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '18'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'breaths/min'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '128'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'mmHg'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '74'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'mmHg'	System	03 Sep 2020 12:28:58

US3402194

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:29:09



US3402194

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Sep 2020'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:29:09

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

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)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '15:46'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '2 Sep 2020 15:46'	System	02 Sep 2020 19:49:12



US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'ONCE'	System	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 19:49:12

US3402194

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:29:21

US3402194

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User closed query 'Per GCL Lab Reconciliation: Sample dated 02Sep2020 is recorded under Visit2 Day29 visit in EDC, however a sample is reported under UNSCHEDULED visit dated 02Sep2020 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 10:59:27
Query 'Per GCL Lab Reconciliation: Sample dated 02Sep2020 is recorded under Visit2 Day29 visit in EDC, however a sample is reported under UNSCHEDULED visit dated 02Sep2020 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Dates are correct as is will correct with PPD' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:31:50
User opened query 'Per GCL Lab Reconciliation: Sample dated 02Sep2020 is recorded under Visit2 Day29 visit in EDC, however a sample is reported under UNSCHEDULED visit dated 02Sep2020 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 21:22:08
User entered '2 Sep 2020'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:21

US3402194

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '15:32'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:29:21

**US3402194**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '2 Sep 2020 15:32'	System	03 Sep 2020 12:29:21

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:27:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:06:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User closed query 'Per GCL Lab Reconciliation Re query: Swab: Per response, "Correct as is", however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing sample collection date or accession, tracking number and shipped date. Please send a data clarification to update the data. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 07:25:06
Query 'Per GCL Lab Reconciliation Re query: Swab: Per response, "Correct as is", however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing sample collection date or accession, tracking number and shipped date. Please send a data clarification to update the data. Thank you.' answered with 'VISIT 2 WAS PREFORMED ON 02SEP2020. PPD HAS THE SWAB UNDER Requisition ID: 1F623800986' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 18:49:54
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 18:49:50
User entered '02 Sep 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 18:49:50
User opened query 'Per GCL Lab Reconciliation Re query: Swab: Per response, "Correct as is", however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing sample collection date or accession, tracking number and shipped date. Please send a data clarification to update the data. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:12:30
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:13
User closed query 'Per GCL Lab Reconciliation requery: Swab: Thank you for your response, however, please provide accession number for the swab sample and tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 16:45:34



US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:27:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation requery: Swab: Thank you for your response, however, please provide accession number for the swab sample and tracking details in query response for tracking purpose. ' answered with 'SAMPLE WAS SHIPPED ON SEP 03 2020 HOWEVER WE ARE UNABLE TO LOCATE THE AIRWAY BILL. ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:35:38
User opened query 'Per GCL Lab Reconciliation requery: Swab: Thank you for your response, however, please provide accession number for the swab sample and tracking details in query response for tracking purpose. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 09:03:29
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02-SEP-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample for 02-SEP-2020 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)	18 Dec 2020 07:59:13
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02-SEP-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample for 02-SEP-2020 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 'Date correct as is a dcr will be sent to correct report date.' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	17 Dec 2020 18:07:57
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02-SEP-2020 is recorded under Visit 2 Day 29 in EDC, however, swab sample for 02-SEP-2020 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 05:08:19

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:27:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab recon: Swab: Sample collection date 02-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD portal Kindly confirm if swab sample was collected on 02-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:20:24
Query 'Per GCL Lab recon: Swab: Sample collection date 02-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD portal Kindly confirm if swab sample was collected on 02-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal.' answered with 'Correct as is' (Site from DM).	Jennifer Molstead (b) (4)	19 Nov 2020 12:09:31
User opened query 'Per GCL Lab recon: Swab: Sample collection date 02-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD portal Kindly confirm if swab sample was collected on 02-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:59:57
User entered '2 Sep 2020'	Traci Hull (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:06:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

**US3402194**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:27:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:06:23
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:06:23
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '15:36'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:06:23
User entered '02 Sep 2020 15:36'	System	12 Apr 2021 18:49:50
User entered '2 Sep 2020 15:36'	System	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:06:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:06:23
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:29:35



US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:06:23
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:06:23
User entered empty.	System	03 Sep 2020 12:29:35

US3402194

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:29:39

**US3402194**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '1'	System	03 Sep 2020 12:29:39

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:30:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85fbec54-c9e8-4f7d-a05e-b30b29bd8106' User entered 'Yes (Y)'	System	02 Sep 2020 20:31:26
	System	02 Sep 2020 20:31:26

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:31:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85fbec54-c9e8-4f7d-a05e-b30b29bd8106' User entered '98.6'	System	02 Sep 2020 20:31:26
	System	02 Sep 2020 20:31:26

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:31:15', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85fbec54-c9e8-4f7d-a05e-b30b29bd8106'	System	02 Sep 2020 20:31:26
User entered 'No (N)'	System	02 Sep 2020 20:31:26



US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:31:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85fbec54-c9e8-4f7d-a05e-b30b29bd8106' User entered '02 Sep 2020 16:31'	System	02 Sep 2020 20:31:26
	System	02 Sep 2020 20:31:26

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Sep 2020 16:06'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Sep 2020 18:36'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a0049254-43d5-4f53-ac4e-b8871fbc8b4b' User entered 'Yes (Y)'	System	02 Sep 2020 23:37:21
	System	02 Sep 2020 23:37:21

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a0049254-43d5-4f53-ac4e-b8871fbc8b4b' User entered '98.6'	System	02 Sep 2020 23:37:21
	System	02 Sep 2020 23:37:21

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a0049254-43d5-4f53-ac4e-b8871fbc8b4b' User entered 'No (N)'	System	02 Sep 2020 23:37:21
	System	02 Sep 2020 23:37:21

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a0049254-43d5-4f53-ac4e-b8871fbc8b4b' User entered '02 Sep 2020 19:37'	System	02 Sep 2020 23:37:21
	System	02 Sep 2020 23:37:21



US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Sep 2020 19:31'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 2'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:31:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c5a49e68-da51-4b15-8310-bb99dc3e288d' User entered 'Yes (Y)'	System	04 Sep 2020 14:32:09
	System	04 Sep 2020 14:32:09

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:31:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c5a49e68-da51-4b15-8310-bb99dc3e288d' User entered '98.6'	System	04 Sep 2020 14:32:09
	System	04 Sep 2020 14:32:09

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:31:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c5a49e68-da51-4b15-8310-bb99dc3e288d' User entered 'No (N)'	System	04 Sep 2020 14:32:09
	System	04 Sep 2020 14:32:09

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:03', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c5a49e68-da51-4b15-8310-bb99dc3e288d' User entered '04 Sep 2020 10:32'	System	04 Sep 2020 14:32:09
	System	04 Sep 2020 14:32:09

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:49:12



US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 3'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:02:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '60ca8057-751f-4300-98b8-6fe9008623c5' User entered 'Yes (Y)'	System	05 Sep 2020 14:03:05
	System	05 Sep 2020 14:03:05

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:02:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '60ca8057-751f-4300-98b8-6fe9008623c5' User entered '98.6'	System	05 Sep 2020 14:03:05
	System	05 Sep 2020 14:03:05

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:02:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '60ca8057-751f-4300-98b8-6fe9008623c5' User entered 'No (N)'	System	05 Sep 2020 14:03:05
	System	05 Sep 2020 14:03:05

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '60ca8057-751f-4300-98b8-6fe9008623c5' User entered '05 Sep 2020 10:03'	System	05 Sep 2020 14:03:05
	System	05 Sep 2020 14:03:05

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:49:12



US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 4'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:21:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bbd0c63b-ca9c-4fa2-869c-812263743967' User entered 'Yes (Y)'	System	05 Sep 2020 16:22:15
	System	05 Sep 2020 16:22:15

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:07', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bbd0c63b-ca9c-4fa2-869c-812263743967' User entered '98.6'	System	05 Sep 2020 16:22:15
	System	05 Sep 2020 16:22:15

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:11', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bbd0c63b-ca9c-4fa2-869c-812263743967'	System	05 Sep 2020 16:22:15
User entered 'No (N)'	System	05 Sep 2020 16:22:15

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bbd0c63b-ca9c-4fa2-869c-812263743967' User entered '05 Sep 2020 12:22'	System	05 Sep 2020 16:22:15
	System	05 Sep 2020 16:22:15

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 5'	System	02 Sep 2020 19:49:12



US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:32:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c250db33-d00e-4cd0-a761-3abcb08907c6' User entered 'Yes (Y)'	System	06 Sep 2020 21:33:07
	System	06 Sep 2020 21:33:07

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:32:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c250db33-d00e-4cd0-a761-3abcb08907c6' User entered '98.6'	System	06 Sep 2020 21:33:07
	System	06 Sep 2020 21:33:07

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:02', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c250db33-d00e-4cd0-a761-3abcb08907c6' User entered 'No (N)'	System	06 Sep 2020 21:33:07
	System	06 Sep 2020 21:33:07

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:04', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c250db33-d00e-4cd0-a761-3abcb08907c6' User entered '06 Sep 2020 17:33'	System	06 Sep 2020 21:33:07
	System	06 Sep 2020 21:33:07

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 6'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:31:55', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '48e7ca20-8cd9-4469-a6f6-9c7762f1d170' User entered 'Yes (Y)'	System	08 Sep 2020 00:32:11
	System	08 Sep 2020 00:32:11



US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:02', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '48e7ca20-8cd9-4469-a6f6-9c7762f1d170' User entered '98.6'	System	08 Sep 2020 00:32:11
	System	08 Sep 2020 00:32:11

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:06', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '48e7ca20-8cd9-4469-a6f6-9c7762f1d170' User entered 'No (N)'	System	08 Sep 2020 00:32:11
	System	08 Sep 2020 00:32:11

**US3402194**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:27:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '48e7ca20-8cd9-4469-a6f6-9c7762f1d170' User entered '07 Sep 2020 20:32'	System	08 Sep 2020 00:32:11
	System	08 Sep 2020 00:32:11

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 7'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7312c248-5ded-4a80-964d-37f64b047db9' User entered 'Yes (Y)'	System	08 Sep 2020 16:03:24
	System	08 Sep 2020 16:03:24

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7312c248-5ded-4a80-964d-37f64b047db9' User entered '98.6'	System	08 Sep 2020 16:03:24
	System	08 Sep 2020 16:03:24



US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7312c248-5ded-4a80-964d-37f64b047db9'	System	08 Sep 2020 16:03:24
User entered 'No (N)'	System	08 Sep 2020 16:03:24

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7312c248-5ded-4a80-964d-37f64b047db9' User entered '08 Sep 2020 12:02'	System	08 Sep 2020 16:03:24
	System	08 Sep 2020 16:03:24

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:31:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c567ee74-0d0d-4c5b-a73b-aa22b31248af' User entered 'None (1)'	System	02 Sep 2020 20:32:16
	System	02 Sep 2020 20:32:16

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:31:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c567ee74-0d0d-4c5b-a73b-aa22b31248af' User entered 'No (N)'	System	02 Sep 2020 20:32:16
	System	02 Sep 2020 20:32:16

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:03', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c567ee74-0d0d-4c5b-a73b-aa22b31248af' User entered 'No (N)'	System	02 Sep 2020 20:32:16
	System	02 Sep 2020 20:32:16



US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c567ee74-0d0d-4c5b-a73b-aa22b31248af'	System	02 Sep 2020 20:32:16
User entered 'None (1)'	System	02 Sep 2020 20:32:16

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c567ee74-0d0d-4c5b-a73b-aa22b31248af' User entered '02 Sep 2020 16:32'	System	02 Sep 2020 20:32:16
	System	02 Sep 2020 20:32:16

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Sep 2020 16:06'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Sep 2020 18:36'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '36287c6e-8e12-4302-aa60-c8683192de42'	System	02 Sep 2020 23:37:44
User entered 'None (1)'	System	02 Sep 2020 23:37:44

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '36287c6e-8e12-4302-aa60-c8683192de42'	System	02 Sep 2020 23:37:44
User entered 'No (N)'	System	02 Sep 2020 23:37:44

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:33', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '36287c6e-8e12-4302-aa60-c8683192de42'	System	02 Sep 2020 23:37:44
User entered 'No (N)'	System	02 Sep 2020 23:37:44



US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:38', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '36287c6e-8e12-4302-aa60-c8683192de42'	System	02 Sep 2020 23:37:44
User entered 'None (1)'	System	02 Sep 2020 23:37:44

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '36287c6e-8e12-4302-aa60-c8683192de42' User entered '02 Sep 2020 19:37'	System	02 Sep 2020 23:37:44
	System	02 Sep 2020 23:37:44

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Sep 2020 19:31'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 2'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '161ec10d-80c5-461c-843c-6a11853dfe85'	System	04 Sep 2020 14:32:32
User entered 'None (1)'	System	04 Sep 2020 14:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '161ec10d-80c5-461c-843c-6a11853dfe85' User entered 'No (N)'	System	04 Sep 2020 14:32:32
	System	04 Sep 2020 14:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '161ec10d-80c5-461c-843c-6a11853dfe85'	System	04 Sep 2020 14:32:32
User entered 'No (N)'	System	04 Sep 2020 14:32:32



US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '161ec10d-80c5-461c-843c-6a11853dfe85'	System	04 Sep 2020 14:32:32
User entered 'None (1)'	System	04 Sep 2020 14:32:32

**US3402194**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:27:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:28', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '161ec10d-80c5-461c-843c-6a11853dfe85' User entered '04 Sep 2020 10:32'	System	04 Sep 2020 14:32:32
	System	04 Sep 2020 14:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 3'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2673107a-82b9-4cfe-a642-5ac41a2719c8'	System	05 Sep 2020 14:03:21
User entered 'None (1)'	System	05 Sep 2020 14:03:21

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:12', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2673107a-82b9-4cfe-a642-5ac41a2719c8'	System	05 Sep 2020 14:03:21
User entered 'No (N)'	System	05 Sep 2020 14:03:21

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2673107a-82b9-4cfe-a642-5ac41a2719c8' User entered 'No (N)'	System	05 Sep 2020 14:03:21
	System	05 Sep 2020 14:03:21



US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2673107a-82b9-4cfe-a642-5ac41a2719c8'	System	05 Sep 2020 14:03:21
User entered 'None (1)'	System	05 Sep 2020 14:03:21

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:18', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '2673107a-82b9-4cfe-a642-5ac41a2719c8' User entered '05 Sep 2020 10:03'	System	05 Sep 2020 14:03:21
	System	05 Sep 2020 14:03:21

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 4'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1e81075d-b92a-440a-98ad-6aadec187300'	System	05 Sep 2020 16:22:34
User entered 'None (1)'	System	05 Sep 2020 16:22:34

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1e81075d-b92a-440a-98ad-6aadec187300' User entered 'No (N)'	System	05 Sep 2020 16:22:34
	System	05 Sep 2020 16:22:34

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1e81075d-b92a-440a-98ad-6aadec187300' User entered 'No (N)'	System	05 Sep 2020 16:22:34
	System	05 Sep 2020 16:22:34



US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1e81075d-b92a-440a-98ad-6aadec187300'	System	05 Sep 2020 16:22:34
User entered 'None (1)'	System	05 Sep 2020 16:22:34

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T12:22:31', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1e81075d-b92a-440a-98ad-6aadec187300' User entered '05 Sep 2020 12:22'	System	05 Sep 2020 16:22:34
	System	05 Sep 2020 16:22:34

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 5'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:11', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'debd0251-c14d-40a2-a546-a3e67aad0dd0'	System	06 Sep 2020 21:33:30
User entered 'None (1)'	System	06 Sep 2020 21:33:30

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'debd0251-c14d-40a2-a546-a3e67aad0dd0' User entered 'No (N)'	System	06 Sep 2020 21:33:30
	System	06 Sep 2020 21:33:30

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'debd0251-c14d-40a2-a546-a3e67aad0dd0' User entered 'No (N)'	System	06 Sep 2020 21:33:30
	System	06 Sep 2020 21:33:30



US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'debd0251-c14d-40a2-a546-a3e67aad0dd0'	System	06 Sep 2020 21:33:30
User entered 'None (1)'	System	06 Sep 2020 21:33:30

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:26', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'debd0251-c14d-40a2-a546-a3e67aad0dd0' User entered '06 Sep 2020 17:33'	System	06 Sep 2020 21:33:30
	System	06 Sep 2020 21:33:30

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 6'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'eb7d98c3-30df-44f2-bd75-0ffeb9600dbc'	System	08 Sep 2020 00:32:32
User entered 'None (1)'	System	08 Sep 2020 00:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'eb7d98c3-30df-44f2-bd75-0ffeb9600dbc' User entered 'No (N)'	System	08 Sep 2020 00:32:32
	System	08 Sep 2020 00:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:21', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'eb7d98c3-30df-44f2-bd75-0ffeb9600dbc' User entered 'No (N)'	System	08 Sep 2020 00:32:32
	System	08 Sep 2020 00:32:32



US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'eb7d98c3-30df-44f2-bd75-0ffeb9600dbc'	System	08 Sep 2020 00:32:32
User entered 'None (1)'	System	08 Sep 2020 00:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'eb7d98c3-30df-44f2-bd75-0ffeb9600dbc' User entered '07 Sep 2020 20:32'	System	08 Sep 2020 00:32:32
	System	08 Sep 2020 00:32:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 7'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:32', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'aedaf888-d09b-48e6-b9a5-4a43e908a991'	System	08 Sep 2020 16:03:32
User entered 'None (1)'	System	08 Sep 2020 16:03:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:35', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'aedaf888-d09b-48e6-b9a5-4a43e908a991'	System	08 Sep 2020 16:03:32
User entered 'No (N)'	System	08 Sep 2020 16:03:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:36', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'aedaf888-d09b-48e6-b9a5-4a43e908a991'	System	08 Sep 2020 16:03:32
User entered 'No (N)'	System	08 Sep 2020 16:03:32



US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:38', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'aedaf888-d09b-48e6-b9a5-4a43e908a991'	System	08 Sep 2020 16:03:32
User entered 'None (1)'	System	08 Sep 2020 16:03:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'aedaf888-d09b-48e6-b9a5-4a43e908a991' User entered '08 Sep 2020 12:02'	System	08 Sep 2020 16:03:32
	System	08 Sep 2020 16:03:32

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e' User entered 'None (0)'	System	02 Sep 2020 20:32:51
	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e' User entered 'None (0)'	System	02 Sep 2020 20:32:51
	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e' User entered 'None (0)'	System	02 Sep 2020 20:32:51
	System	02 Sep 2020 20:32:51



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:31', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e' User entered 'None (0)'	System	02 Sep 2020 20:32:51
	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:34', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e' User entered 'None (0)'	System	02 Sep 2020 20:32:51
	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e' User entered 'None (0)'	System	02 Sep 2020 20:32:51
	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:45', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e' User entered 'No (N)'	System	02 Sep 2020 20:32:51
	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T16:32:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '7a5cbc2b-214f-46bc-9e00-0061dd4c5f7e' User entered '02 Sep 2020 16:32'	System	02 Sep 2020 20:32:51
	System	02 Sep 2020 20:32:51

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Sep 2020 16:06'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Sep 2020 18:36'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:49:12



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9'	System	02 Sep 2020 23:38:05
User entered 'None (0)'	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9' User entered 'None (0)'	System	02 Sep 2020 23:38:05
	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9' User entered 'None (0)'	System	02 Sep 2020 23:38:05
	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9' User entered 'None (0)'	System	02 Sep 2020 23:38:05
	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9' User entered 'None (0)'	System	02 Sep 2020 23:38:05
	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:37:56', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9' User entered 'None (0)'	System	02 Sep 2020 23:38:05
	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:38:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9'	System	02 Sep 2020 23:38:05
User entered 'No (N)'	System	02 Sep 2020 23:38:05

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-02T19:38:03', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'df93d7fb-8bc4-4bb3-95b8-cda0e1b573e9' User entered '02 Sep 2020 19:38'	System	02 Sep 2020 23:38:05
	System	02 Sep 2020 23:38:05



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '02 Sep 2020 19:31'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 2'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:33', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3' User entered 'None (0)'	System	04 Sep 2020 14:32:56
	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:35', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3' User entered 'None (0)'	System	04 Sep 2020 14:32:56
	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3' User entered 'None (0)'	System	04 Sep 2020 14:32:56
	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3' User entered 'None (0)'	System	04 Sep 2020 14:32:56
	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:42', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3' User entered 'None (0)'	System	04 Sep 2020 14:32:56
	System	04 Sep 2020 14:32:56



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:44', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3' User entered 'None (0)'	System	04 Sep 2020 14:32:56
	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3'	System	04 Sep 2020 14:32:56
User entered 'No (N)'	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-04T10:32:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1c77c699-4b3d-4cfb-94ce-cb2b09b7d5c3' User entered '04 Sep 2020 10:32'	System	04 Sep 2020 14:32:56
	System	04 Sep 2020 14:32:56

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 3'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:22', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a' User entered 'None (0)'	System	05 Sep 2020 14:03:44
	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a' User entered 'None (0)'	System	05 Sep 2020 14:03:44
	System	05 Sep 2020 14:03:44



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a' User entered 'None (0)'	System	05 Sep 2020 14:03:44
	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a' User entered 'None (0)'	System	05 Sep 2020 14:03:44
	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:31', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a' User entered 'None (0)'	System	05 Sep 2020 14:03:44
	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:33', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a' User entered 'None (0)'	System	05 Sep 2020 14:03:44
	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a' User entered 'No (N)'	System	05 Sep 2020 14:03:44
	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T10:03:42', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ad69710e-748f-432a-90cb-2be20845c71a' User entered '05 Sep 2020 10:03'	System	05 Sep 2020 14:03:44
	System	05 Sep 2020 14:03:44

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:49:12



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 4'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b' User entered 'None (0)'	System	05 Sep 2020 17:13:27
	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:12', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b' User entered 'None (0)'	System	05 Sep 2020 17:13:27
	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:14', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b' User entered 'None (0)'	System	05 Sep 2020 17:13:27
	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b' User entered 'None (0)'	System	05 Sep 2020 17:13:27
	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b' User entered 'None (0)'	System	05 Sep 2020 17:13:27
	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:21', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b' User entered 'None (0)'	System	05 Sep 2020 17:13:27
	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b' User entered 'No (N)'	System	05 Sep 2020 17:13:27
	System	05 Sep 2020 17:13:27



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-05T13:13:26', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '27f4db82-9c57-405d-a782-d9ac2404ee8b' User entered '05 Sep 2020 13:13'	System	05 Sep 2020 17:13:27
	System	05 Sep 2020 17:13:27

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 5'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:36', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7' User entered 'None (0)'	System	06 Sep 2020 21:33:58
	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:38', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7' User entered 'None (0)'	System	06 Sep 2020 21:33:58
	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:39', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7' User entered 'None (0)'	System	06 Sep 2020 21:33:58
	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7' User entered 'None (0)'	System	06 Sep 2020 21:33:58
	System	06 Sep 2020 21:33:58



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:44', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7' User entered 'None (0)'	System	06 Sep 2020 21:33:58
	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7' User entered 'None (0)'	System	06 Sep 2020 21:33:58
	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7'	System	06 Sep 2020 21:33:58
User entered 'No (N)'	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-06T17:33:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '50747a51-e9c0-47bf-b0b7-1a3dcbabefe7' User entered '06 Sep 2020 17:33'	System	06 Sep 2020 21:33:58
	System	06 Sep 2020 21:33:58

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 6'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:32:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:03', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:06', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:09', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:12', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'None (0)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3'	System	08 Sep 2020 00:33:40
User entered 'No (N)'	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-07T20:33:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '196fff97-ad94-4679-b8f9-46dfc6ad4bf3' User entered '07 Sep 2020 20:33'	System	08 Sep 2020 00:33:40
	System	08 Sep 2020 00:33:40

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:49:12



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Sep 2020 19:49:12
User entered 'Day 7'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:44', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:47', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736' User entered 'None (0)'	System	08 Sep 2020 16:03:49
	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:52', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'None (0)'	System	08 Sep 2020 16:03:49



US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:56', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736'	System	08 Sep 2020 16:03:49
User entered 'No (N)'	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-09-08T12:02:59', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52efdf0e-c6e5-489a-9a2b-9ad55eb64736' User entered '08 Sep 2020 12:02'	System	08 Sep 2020 16:03:49
	System	08 Sep 2020 16:03:49

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:49:12

US3402194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:49:12

US3402194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 13:49:13

US3402194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '9 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 13:49:13
	(b) (4)	

US3402194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 13:49:13

US3402194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 13:49:13
	(b) (4)	



US3402194

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 13:49:17

US3402194

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'I'	System	09 Sep 2020 13:49:17

US3402194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	17 Sep 2020 11:22:58

US3402194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '16 Sep 2020'	(b) (4) Traci Hull (b) (4)	17 Sep 2020 11:22:58

US3402194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	17 Sep 2020 11:22:58

US3402194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	17 Sep 2020 11:22:58

US3402194

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	17 Sep 2020 11:22:48

**US3402194**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '1'	System	17 Sep 2020 11:22:48



**US3402194**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	23 Sep 2020 13:57:41

**US3402194**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:28**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '23 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	23 Sep 2020 13:57:41

US3402194

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	23 Sep 2020 13:57:41

US3402194

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Tammy Kohn (b) (4)	23 Sep 2020 13:57:41
	(b) (4)	

US3402194

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	23 Sep 2020 13:57:45
	(b) (4)	

US3402194

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '1'	System	23 Sep 2020 13:57:45

US3402194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:47:48

US3402194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '30 Sep 2020'	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:47:48



US3402194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:47:48

US3402194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'VISIT3'	System	30 Sep 2020 18:47:48

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '30 Sep 2020'	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '14:11'	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '30 Sep 2020 14:11'	System	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
	(b) (4)	
User entered '36.8' C	Traci Hull (b) (4)	30 Sep 2020 18:51:18
	(b) (4)	

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:51:18
	(b) (4)	



US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '84'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'bpm'	System	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '14'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'breaths/min'	System	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '127'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'mmHg'	System	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '61'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:18



US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered 'mmHg'	System	30 Sep 2020 18:51:18

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10

US3402194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10

US3402194

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:51:24

US3402194

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered empty.	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:51:24

US3402194

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:51:37

US3402194

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day57 Visit with date 02OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 06:44:11
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day57 Visit with date 02OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' answered with 'DATA WAS UPDATED BY THE LAB.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 12:17:41
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day57 Visit with date 02OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:04:02
User entered '30 Sep 2020'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:37

**US3402194**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered '14:16'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Sep 2020 18:51:37



**US3402194**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '30 Sep 2020 14:16'	System	30 Sep 2020 18:51:37

US3402194

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:13
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:47:39

**US3402194**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '1'	System	30 Sep 2020 18:47:39

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 64'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-02T00:04:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '624c8698-2ac9-4442-8a3d-5d37c950a9d0'	System	02 Oct 2020 04:05:19
User entered 'No (N)'	System	02 Oct 2020 04:05:19

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-02T00:05:02', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '624c8698-2ac9-4442-8a3d-5d37c950a9d0'	System	02 Oct 2020 04:05:19
User entered 'No (N)'	System	02 Oct 2020 04:05:19

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-02T00:05:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '624c8698-2ac9-4442-8a3d-5d37c950a9d0' User entered '02 Oct 2020 00:05:16'	System	02 Oct 2020 04:05:19
	System	02 Oct 2020 04:05:19

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '02 Oct 2020 00:01'	System	02 Aug 2020 20:57:32



US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '06 Oct 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 71'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-09T00:01:36', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '42d1677c-2f81-4109-98e8-42512721066d'	System	09 Oct 2020 04:02:06
User entered 'No (N)'	System	09 Oct 2020 04:02:06

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-09T00:01:43', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '42d1677c-2f81-4109-98e8-42512721066d'	System	09 Oct 2020 04:02:06
User entered 'No (N)'	System	09 Oct 2020 04:02:06

**US3402194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-09T00:02:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '42d1677c-2f81-4109-98e8-42512721066d' User entered '09 Oct 2020 00:02:01'	System	09 Oct 2020 04:02:06
	System	09 Oct 2020 04:02:06

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '09 Oct 2020 00:01'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '13 Oct 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 78'	System	02 Aug 2020 20:57:32



US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-16T00:01:36', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c9d982f7-7801-403a-8c55-6068ed6fe959'	System	16 Oct 2020 04:01:50
User entered 'No (N)'	System	16 Oct 2020 04:01:50

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-16T00:01:43', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c9d982f7-7801-403a-8c55-6068ed6fe959'	System	16 Oct 2020 04:01:50
User entered 'No (N)'	System	16 Oct 2020 04:01:50

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-10-16T00:01:48', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c9d982f7-7801-403a-8c55-6068ed6fe959' User entered '16 Oct 2020 00:01:48'	System	16 Oct 2020 04:01:50
	System	16 Oct 2020 04:01:50

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '16 Oct 2020 00:01'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '20 Oct 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 92'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-03T12:31:30', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a6442a7f-4354-40fd-8f5b-a814e9d6044b'	System	03 Nov 2020 17:32:07
User entered 'No (N)'	System	03 Nov 2020 17:32:07

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-03T12:31:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a6442a7f-4354-40fd-8f5b-a814e9d6044b'	System	03 Nov 2020 17:32:07
User entered 'No (N)'	System	03 Nov 2020 17:32:07



US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-03T12:32:04', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a6442a7f-4354-40fd-8f5b-a814e9d6044b' User entered '03 Nov 2020 12:32:04'	System	03 Nov 2020 17:32:07
	System	03 Nov 2020 17:32:07

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '30 Oct 2020 00:01'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '03 Nov 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 99'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-06T00:01:51', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ddb9f50b-5bc1-4d0e-a518-9904b94be4b4' User entered 'No (N)'	System	06 Nov 2020 05:02:15
	System	06 Nov 2020 05:02:15

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-06T00:02:08', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ddb9f50b-5bc1-4d0e-a518-9904b94be4b4'	System	06 Nov 2020 05:02:15
User entered 'No (N)'	System	06 Nov 2020 05:02:15

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-06T00:02:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ddb9f50b-5bc1-4d0e-a518-9904b94be4b4' User entered '06 Nov 2020 00:02:13'	System	06 Nov 2020 05:02:15
	System	06 Nov 2020 05:02:15

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '06 Nov 2020 00:01'	System	02 Aug 2020 20:57:32



US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '10 Nov 2020 23:59'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered 'Day 106'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T08:59:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered 'Yes (Y)'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T08:59:55', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered 'Yes (Y)'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:00:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be'	System	13 Nov 2020 14:02:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:00:47', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered 'Yes (Y)'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '1'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26



US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '1'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26



US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '0'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '1'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:29', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '1'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

**US3402194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be'	System	13 Nov 2020 14:02:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 14:02:26



US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:01:56', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered 'No (N)'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-13T09:02:17', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a221e258-3ef8-4d78-b064-a1e94daba8be' User entered '13 Nov 2020 09:02:17'	System	13 Nov 2020 14:02:26
	System	13 Nov 2020 14:02:26

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '13 Nov 2020 00:01'	System	02 Aug 2020 20:57:32

US3402194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:05
Data entry locked.	System	02 Aug 2020 20:57:32
User entered '17 Nov 2020 23:59'	System	02 Aug 2020 20:57:32

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:35:01



US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-25T07:50:32', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'befb5265-d3df-423e-8fcb-1a6edf83d4ad'	System	25 Nov 2020 12:51:22
User entered 'Yes (Y)'	System	25 Nov 2020 12:51:22

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-25T07:50:41', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'befb5265-d3df-423e-8fcb-1a6edf83d4ad'	System	25 Nov 2020 12:51:22
User entered 'Yes (Y)'	System	25 Nov 2020 12:51:22

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

Please 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-25T07:50:46', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'befb5265-d3df-423e-8fcb-1a6edf83d4ad'	System	25 Nov 2020 12:51:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 12:51:22

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-25T07:50:54', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'befb5265-d3df-423e-8fcb-1a6edf83d4ad'	System	25 Nov 2020 12:51:22
User entered 'No (N)'	System	25 Nov 2020 12:51:22

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-25T07:51:01', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'befb5265-d3df-423e-8fcb-1a6edf83d4ad'	System	25 Nov 2020 12:51:22
User entered 'Yes (Y)'	System	25 Nov 2020 12:51:22

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

Please 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-25T07:51:04', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'befb5265-d3df-423e-8fcb-1a6edf83d4ad'	System	25 Nov 2020 12:51:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 12:51:22

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-11-25T07:51:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'befb5265-d3df-423e-8fcb-1a6edf83d4ad' User entered '25 Nov 2020 07:51:13'	System	25 Nov 2020 12:51:22
	System	25 Nov 2020 12:51:22

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-03T12:00:26', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c580de6a-ae00-4274-bd93-c44bf4a42260'	System	03 Dec 2020 17:00:47
User entered 'No (N)'	System	03 Dec 2020 17:00:47

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-03T12:00:39', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c580de6a-ae00-4274-bd93-c44bf4a42260'	System	03 Dec 2020 17:00:47
User entered 'No (N)'	System	03 Dec 2020 17:00:47

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-03T12:00:43', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'c580de6a-ae00-4274-bd93-c44bf4a42260' User entered '03 Dec 2020 12:00:43'	System	03 Dec 2020 17:00:47
	System	03 Dec 2020 17:00:47

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:35:01



US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-12T11:59:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '471231ce-c75c-4bc6-b432-6118005236e7' User entered 'No (N)'	System	12 Dec 2020 16:59:29
	System	12 Dec 2020 16:59:29

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-12T11:59:24', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '471231ce-c75c-4bc6-b432-6118005236e7' User entered 'No (N)'	System	12 Dec 2020 16:59:29
	System	12 Dec 2020 16:59:29

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-12T11:59:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '471231ce-c75c-4bc6-b432-6118005236e7'	System	12 Dec 2020 16:59:29
User entered '12 Dec 2020 11:59:27'	System	12 Dec 2020 16:59:29

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-17T17:10:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1b4918e6-af17-48bc-84ba-f72a4a2353b4'	System	17 Dec 2020 22:10:52
User entered 'No (N)'	System	17 Dec 2020 22:10:52

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-17T17:10:44', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1b4918e6-af17-48bc-84ba-f72a4a2353b4'	System	17 Dec 2020 22:10:52
User entered 'No (N)'	System	17 Dec 2020 22:10:52



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-17T17:10:49', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '1b4918e6-af17-48bc-84ba-f72a4a2353b4' User entered '17 Dec 2020 17:10:49'	System	17 Dec 2020 22:10:52
	System	17 Dec 2020 22:10:52

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-22T00:06:44', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '33e0cc18-71d7-4629-8763-8953e5f617c2'	System	22 Dec 2020 05:06:58
User entered 'No (N)'	System	22 Dec 2020 05:06:58

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-22T00:06:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '33e0cc18-71d7-4629-8763-8953e5f617c2'	System	22 Dec 2020 05:06:58
User entered 'No (N)'	System	22 Dec 2020 05:06:58

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-22T00:06:56', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '33e0cc18-71d7-4629-8763-8953e5f617c2' User entered '22 Dec 2020 00:06:56'	System	22 Dec 2020 05:06:58
	System	22 Dec 2020 05:06:58

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-29T21:51:53', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bcfc41c6-5aee-4fd7-a7b9-f9ef02dfde5e'	System	30 Dec 2020 05:52:04
User entered 'No (N)'	System	30 Dec 2020 05:52:04

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-29T21:51:57', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bcfc41c6-5aee-4fd7-a7b9-f9ef02dfde5e'	System	30 Dec 2020 05:52:04
User entered 'No (N)'	System	30 Dec 2020 05:52:04

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2020-12-29T21:52:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'bcfc41c6-5aee-4fd7-a7b9-f9ef02dfde5e'	System	30 Dec 2020 05:52:04
User entered '29 Dec 2020 21:52:00'	System	30 Dec 2020 05:52:04

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:35:01



US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-08T18:00:51', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '923e2ebd-b1f1-46c2-bc8c-096d715b95af' User entered 'No (N)'	System	08 Jan 2021 23:01:12
	System	08 Jan 2021 23:01:12

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-08T18:00:55', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '923e2ebd-b1f1-46c2-bc8c-096d715b95af'	System	08 Jan 2021 23:01:12
User entered 'No (N)'	System	08 Jan 2021 23:01:12

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-08T18:00:58', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '923e2ebd-b1f1-46c2-bc8c-096d715b95af' User entered '08 Jan 2021 18:00:58'	System	08 Jan 2021 23:01:12
	System	08 Jan 2021 23:01:12

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-12T00:08:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85868882-65c6-4921-8efe-ff10022ee832'	System	12 Jan 2021 05:08:40
User entered 'No (N)'	System	12 Jan 2021 05:08:40

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-12T00:08:27', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85868882-65c6-4921-8efe-ff10022ee832'	System	12 Jan 2021 05:08:40
User entered 'No (N)'	System	12 Jan 2021 05:08:40



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-12T00:08:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '85868882-65c6-4921-8efe-ff10022ee832'	System	12 Jan 2021 05:08:40
User entered '12 Jan 2021 00:08:37'	System	12 Jan 2021 05:08:40

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-22T16:54:09', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f6bcb584-f451-4746-9a80-5e2f3bb02425' User entered 'No (N)'	System	22 Jan 2021 21:54:18
	System	22 Jan 2021 21:54:18

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-22T16:54:11', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f6bcb584-f451-4746-9a80-5e2f3bb02425'	System	22 Jan 2021 21:54:18
User entered 'No (N)'	System	22 Jan 2021 21:54:18

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-22T16:54:15', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'f6bcb584-f451-4746-9a80-5e2f3bb02425' User entered '22 Jan 2021 16:54:15'	System	22 Jan 2021 21:54:18
	System	22 Jan 2021 21:54:18

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-28T12:06:10', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e7a0e9ff-cab2-4867-a3dc-12fb5e7d484c'	System	28 Jan 2021 17:10:05
User entered 'No (N)'	System	28 Jan 2021 17:10:05

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-28T12:06:13', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e7a0e9ff-cab2-4867-a3dc-12fb5e7d484c'	System	28 Jan 2021 17:10:05
User entered 'No (N)'	System	28 Jan 2021 17:10:05

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-01-28T12:06:18', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'e7a0e9ff-cab2-4867-a3dc-12fb5e7d484c' User entered '28 Jan 2021 12:06:18'	System	28 Jan 2021 17:10:05
	System	28 Jan 2021 17:10:05

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:35:01



US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-03T10:56:16', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '128df4c8-5926-4882-b693-92324399f8f2'	System	03 Feb 2021 15:56:26
User entered 'No (N)'	System	03 Feb 2021 15:56:26

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-03T10:56:19', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '128df4c8-5926-4882-b693-92324399f8f2'	System	03 Feb 2021 15:56:26
User entered 'No (N)'	System	03 Feb 2021 15:56:26

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-03T10:56:23', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '128df4c8-5926-4882-b693-92324399f8f2'	System	03 Feb 2021 15:56:26
User entered '03 Feb 2021 10:56:23'	System	03 Feb 2021 15:56:26

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-12T17:38:18', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '12734f16-9d41-477b-95b0-0b1da50dea2b'	System	12 Feb 2021 22:38:29
User entered 'No (N)'	System	12 Feb 2021 22:38:29

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-12T17:38:20', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '12734f16-9d41-477b-95b0-0b1da50dea2b'	System	12 Feb 2021 22:38:29
User entered 'No (N)'	System	12 Feb 2021 22:38:29



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-12T17:38:25', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '12734f16-9d41-477b-95b0-0b1da50dea2b'	System	12 Feb 2021 22:38:29
User entered '12 Feb 2021 17:38:25'	System	12 Feb 2021 22:38:29

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-16T00:25:34', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '5bda2e28-b702-487f-b959-49d0d0ef0d65'	System	16 Feb 2021 05:25:42
User entered 'No (N)'	System	16 Feb 2021 05:25:42

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-16T00:25:37', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '5bda2e28-b702-487f-b959-49d0d0ef0d65'	System	16 Feb 2021 05:25:42
User entered 'No (N)'	System	16 Feb 2021 05:25:42

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-16T00:25:39', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '5bda2e28-b702-487f-b959-49d0d0ef0d65' User entered '16 Feb 2021 00:25:39'	System	16 Feb 2021 05:25:42
	System	16 Feb 2021 05:25:42

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-23T00:13:40', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '0bb98c29-2438-4a3d-ba59-51749bf15588'	System	23 Feb 2021 05:13:54
User entered 'No (N)'	System	23 Feb 2021 05:13:54

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-23T00:13:42', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '0bb98c29-2438-4a3d-ba59-51749bf15588'	System	23 Feb 2021 05:13:54
User entered 'No (N)'	System	23 Feb 2021 05:13:54

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-02-23T00:13:50', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '0bb98c29-2438-4a3d-ba59-51749bf15588'	System	23 Feb 2021 05:13:54
User entered '23 Feb 2021 00:13:50'	System	23 Feb 2021 05:13:54

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:35:01



US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-03-02T02:53:01-05:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '466c93da-a88b-48da-9fc8-58b9d2c4d3cb'	System	02 Mar 2021 07:53:12
User entered 'No (N)'	System	02 Mar 2021 07:53:12

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-03-02T02:53:03-05:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '466c93da-a88b-48da-9fc8-58b9d2c4d3cb'	System	02 Mar 2021 07:53:12
User entered 'No (N)'	System	02 Mar 2021 07:53:12

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-03-02T02:53:08-05:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '466c93da-a88b-48da-9fc8-58b9d2c4d3cb' User entered '02 Mar 2021 02:53:08'	System	02 Mar 2021 07:53:12
	System	02 Mar 2021 07:53:12

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-03-30T00:11:13-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a24c9142-41b1-4ecd-ba38-5000c9ad2169'	System	30 Mar 2021 04:11:29
User entered 'No (N)'	System	30 Mar 2021 04:11:29



US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-03-30T00:11:16-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a24c9142-41b1-4ecd-ba38-5000c9ad2169'	System	30 Mar 2021 04:11:29
User entered 'No (N)'	System	30 Mar 2021 04:11:29

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-03-30T00:11:22-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'a24c9142-41b1-4ecd-ba38-5000c9ad2169' User entered '30 Mar 2021 00:11:22'	System	30 Mar 2021 04:11:29
	System	30 Mar 2021 04:11:29

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-06T00:08:41-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ce663094-a82c-4ff2-8672-e4300bdb46fd' User entered 'No (N)'	System	06 Apr 2021 04:08:52
	System	06 Apr 2021 04:08:52

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-06T00:08:44-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ce663094-a82c-4ff2-8672-e4300bdb46fd' User entered 'No (N)'	System	06 Apr 2021 04:08:52
	System	06 Apr 2021 04:08:52

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-06T00:08:48-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: 'ce663094-a82c-4ff2-8672-e4300bdb46fd'	System	06 Apr 2021 04:08:52
User entered '06 Apr 2021 00:08:48'	System	06 Apr 2021 04:08:52



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-13T11:11:26-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '5b30ae16-c9f5-42c8-9a9c-f10d68c6c52c'	System	13 Apr 2021 15:11:36
User entered 'No (N)'	System	13 Apr 2021 15:11:36

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-13T11:11:29-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '5b30ae16-c9f5-42c8-9a9c-f10d68c6c52c'	System	13 Apr 2021 15:11:36
User entered 'No (N)'	System	13 Apr 2021 15:11:36

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-13T11:11:34-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '5b30ae16-c9f5-42c8-9a9c-f10d68c6c52c'	System	13 Apr 2021 15:11:36
User entered '13 Apr 2021 11:11:34'	System	13 Apr 2021 15:11:36

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-22T12:13:49-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '9d71de46-634d-4606-a37b-ca2b856305c8'	System	22 Apr 2021 16:14:13
User entered 'No (N)'	System	22 Apr 2021 16:14:13

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-22T12:13:52-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '9d71de46-634d-4606-a37b-ca2b856305c8'	System	22 Apr 2021 16:14:13
User entered 'No (N)'	System	22 Apr 2021 16:14:13

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-22T12:13:58-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '9d71de46-634d-4606-a37b-ca2b856305c8'	System	22 Apr 2021 16:14:13
User entered '22 Apr 2021 12:13:58'	System	22 Apr 2021 16:14:13

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:35:01

US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

[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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-27T10:38:44-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '985f4d65-1cfe-4f3e-b3cd-b6683d6c19b7'	System	29 Apr 2021 02:15:36
User entered 'No (N)'	System	29 Apr 2021 02:15:36



US3402194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:28

Have you been exposed to someone with 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 (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-27T10:38:46-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '985f4d65-1cfe-4f3e-b3cd-b6683d6c19b7'	System	29 Apr 2021 02:15:36
User entered 'No (N)'	System	29 Apr 2021 02:15:36

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-04-27T10:38:51-04:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '985f4d65-1cfe-4f3e-b3cd-b6683d6c19b7'	System	29 Apr 2021 02:15:36
User entered '27 Apr 2021 10:38:51'	System	29 Apr 2021 02:15:36

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:35:01



**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 11:35:01

**US3402194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:35:01
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 11:35:01

US3402194

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:27:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:22:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-03-02T02:53:29-05:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52bdcfe3-27ab-4fb4-b5d7-b61c7395bd33'	System	02 Mar 2021 07:54:01
User entered 'No (N)'	System	02 Mar 2021 07:54:01

US3402194

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:27:28

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:22:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94FEABF4-415D-453D-A0FF-00674770643E)', Time: '2021-03-02T02:53:57-05:00', User OID: 'PatientReportedOutcome (US3402194)', ODM File OID: '52bdcfe3-27ab-4fb4-b5d7-b61c7395bd33' User entered '02 Mar 2021 02:53:57'	System	02 Mar 2021 07:54:01
	System	02 Mar 2021 07:54:01

US3402194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:19:37
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	26 Oct 2020 17:49:57



US3402194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:19:37
User entered '26 Oct 2020'	(b) (4) Traci Hull (b) (4)	26 Oct 2020 17:49:57

US3402194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:19:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	26 Oct 2020 17:49:57

US3402194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:19:37
User entered empty.	(b) (4) Traci Hull (b) (4)	26 Oct 2020 17:49:57

US3402194

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:19:37
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	26 Oct 2020 17:49:47

US3402194

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:13:10
User entered '1'	System	26 Oct 2020 17:49:47

US3402194

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	08 Dec 2020 23:36:35

US3402194

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	08 Dec 2020 23:36:35

US3402194

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	08 Dec 2020 23:36:35



US3402194

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Subject in convalescent phase'	Jennifer Molstead (b) (4) (b) (4)	08 Dec 2020 23:36:35

US3402194

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	11 Dec 2020 14:46:20

**US3402194**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User entered 'I'	System	11 Dec 2020 14:46:20

US3402194

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	14 Jan 2021 01:04:58

US3402194

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '30 Dec 2020'	(b) (4) Jennifer Molstead (b) (4)	14 Jan 2021 01:04:58

US3402194

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4) (b) (4)	14 Jan 2021 01:04:58

US3402194

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	14 Jan 2021 01:04:58

US3402194

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	14 Jan 2021 01:05:03



US3402194

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User entered '1'	System	14 Jan 2021 01:05:03

US3402194

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:07:22

**US3402194**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:28**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '28 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:07:22

US3402194

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:07:22

US3402194

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered empty.	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:07:22
	(b) (4)	

US3402194

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:07:25

US3402194

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:19
User entered 'I'	System	02 Mar 2021 20:07:25

US3402194

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User closed query 'Per CDM: Thank you for record the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 2 Mar 2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review Reconcile and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 07:43:18
Query 'Per CDM: Thank you for record the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 2 Mar 2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review Reconcile and update as appropriate. ' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 20:17:30
User opened query 'Per CDM: Thank you for record the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 2 Mar 2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:29:35
User closed query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 2 Mar 2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:29:35



US3402194

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 2 Mar 2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' answered with 'correct as is' (Site from DM).	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:24
User opened query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 2 Mar 2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:07:57
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	02 Mar 2021 20:07:44

US3402194

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '2 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:07:44
	(b) (4)	

**US3402194**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:28**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Clinic (Clinic)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:07:44

**US3402194**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User entered 'VISIT4'	System	02 Mar 2021 20:07:44

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	31 Mar 2021 20:10:39
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	30 Mar 2021 18:40:58
	(b) (4)	

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:28
User entered '02 Mar 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 20:10:39
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:40:58

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '12:11' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:10:39
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 18:40:58
	(b) (4)	

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User entered '02 Mar 2021 12:11'	System	31 Mar 2021 20:10:39
User entered empty.	System	30 Mar 2021 18:40:58



US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:28
User entered '36.5' C reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 20:10:39
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:40:58

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:10:39
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 18:40:58
	(b) (4)	

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered empty.	(b) (4) Traci Hull (b) (4)	30 Mar 2021 18:40:58

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '74' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:10:39
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 18:40:58
	(b) (4)	

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User entered 'bpm'	System	31 Mar 2021 20:10:39
User entered empty.	System	30 Mar 2021 18:40:58

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '16' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:10:39
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 18:40:58
	(b) (4)	

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User entered 'breaths/min'	System	31 Mar 2021 20:10:39
User entered empty.	System	30 Mar 2021 18:40:58

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '125' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:10:39
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 18:40:58
	(b) (4)	



US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User entered 'mmHg'	System	31 Mar 2021 20:10:39
User entered empty.	System	30 Mar 2021 18:40:58

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '65' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 20:10:39
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 18:40:58
	(b) (4)	

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User entered 'mmHg'	System	31 Mar 2021 20:10:39
User entered empty.	System	30 Mar 2021 18:40:58

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53

US3402194

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53

US3402194

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:08:26

US3402194

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '2 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:08:26

US3402194

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:08:48



**US3402194**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

*Collection date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '2 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:08:48

US3402194

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '12:29'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:08:48

**US3402194**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User entered '2 Mar 2021 12:29'	System	02 Mar 2021 20:08:48

US3402194

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:09:12

**US3402194**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:53
User entered '1'	System	02 Mar 2021 20:09:12

US3402194

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	30 Mar 2021 18:15:09
	(b) (4)	

US3402194

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
	(b) (4)	
User entered '30 Mar 2021'	Traci Hull (b) (4)	30 Mar 2021 18:15:09
	(b) (4)	

US3402194

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:15:09



**US3402194**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:09
	(b) (4)	

US3402194

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	30 Mar 2021 18:14:58
	(b) (4)	

**US3402194**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:28**

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 18:14:58

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US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:28

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:13
User entered '13 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:36

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:28

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:13
User entered '11:30'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:36

**US3402194**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:27:28**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:49
User entered '13 Nov 2020 11:30'	System	16 Nov 2020 12:58:36

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:28

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:13
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:36

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:28

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:13
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:36



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User closed query 'Please reconcile as AE start date = 03Nov2020. Per CCGs and training provided to all sites symptom log Day 1 = day subject first experienced symptoms. Please add 03Nov2020 - 12Nov2020 beginning on line 7 and then update symptom day # only on lines 1-6.' (Site from CRA). Query 'Please reconcile as AE start date = 03Nov2020. Per CCGs and training provided to all sites symptom log Day 1 = day subject first experienced symptoms. Please add 03Nov2020 - 12Nov2020 beginning on line 7 and then update symptom day # only on lines 1-6.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 04:26:29
User entered 'Day 9 (Day 9)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:39:51
User opened query 'Please reconcile as AE start date = 03Nov2020. Per CCGs and training provided to all sites symptom log Day 1 = day subject first experienced symptoms. Please add 03Nov2020 - 12Nov2020 beginning on line 7 and then update symptom day # only on lines 1-6.' (Site from CRA). User entered 'Day 1 (Day 1)'	Jennifer Molstead (b) (4) (b) (4), (b) (6)	19 Nov 2020 20:34:27
	(b) (4), (b) (6)	19 Nov 2020 13:36:08
	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '14 Nov 2020' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered '12 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User entered '13 Nov 2020'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '99' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered '96' reason for change: New Information	Traci Hull (b) (4)	16 Nov 2020 13:04:35
User entered empty.	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	16 Nov 2020 13:04:35
User entered empty.	System	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '99.0' F reason for change: Data Entry Error	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered '99.3' F	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Moderate (Moderate)'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Moderate (Moderate)'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:39:40
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:39:40
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Mild (Mild)'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:12

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 10 (Day 10)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:34:27
User entered 'Day 2 (Day 2)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '15 Nov 2020' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered '13 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User entered '14 Nov 2020'	Traci Hull (b) (4)	16 Nov 2020 13:02:59



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '94' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered '99'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	16 Nov 2020 13:02:59

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '99.0' F	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:31:35
User closed query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:31:33
Query 'Per source, started 15-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:20:10
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:27
	(b) (4)	
User opened query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:32:28
	Traci Hull (b) (4)	16 Nov 2020 13:02:59
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User closed query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:31:41
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:31:40
Query 'Per source, started 15-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:20:21
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:58
User opened query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:34:28
	(b) (4), (b) (6)	25 Nov 2020 00:31:45
	Traci Hull (b) (4)	16 Nov 2020 13:02:59
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User closed query 'Per source - diarrhea is listed as mild. Please verify and update accordingly' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:51:08
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 15:51:05
Query 'Per source - diarrhea is listed as mild. Please verify and update accordingly' answered with 'data updated' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	27 Nov 2020 12:15:01
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	27 Nov 2020 12:14:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	27 Nov 2020 12:14:53
User opened query 'Per source - diarrhea is listed as mild. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 13:34:23
Query 'Per source - diarrhea is listed as mild. Please verify and update accordingly. ' canceled (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 13:34:13
User opened query 'Per source - diarrhea is listed as mild. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:33:02
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:02:59

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User closed query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:32:22
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 04:31:51
Query 'Per source, started 15-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:20:33
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:19:27
DataPoint Verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:19:27
User opened query 'Per source, started 15-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	(b) (4), (b) (6)	25 Nov 2020 00:31:12
	Traci Hull (b) (4)	16 Nov 2020 13:02:59
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 11 (Day 11)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:34:27
User entered 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '16 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User entered '15 Nov 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '83' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:40:57
User entered '99'	Traci Hull (b) (4)	16 Nov 2020 13:03:25



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '99.0' F	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 13:03:25

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 12 (Day 12)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:34:27
User entered 'Day 4 (Day 4)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '17 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 13:25:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 13:25:42
User entered '16 Nov 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 12:10:26
User entered empty.	System	19 Nov 2020 12:10:26
	Traci Hull (b) (4)	19 Nov 2020 12:10:26
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '92' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:40:57
User entered '83' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 13:25:42
User entered empty.	System	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.9' F reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	Traci Hull (b) (4)	19 Nov 2020 12:10:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 13:25:42
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:10:26



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 13 (Day 13)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:34:27
User entered 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '18 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User entered '17 Nov 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '94' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:40:57
User entered '92'	Traci Hull (b) (4)	19 Nov 2020 12:13:30
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 12:13:30

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '97.3' F	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:13:30

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 14 (Day 14)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:34:27
User entered 'Day 6 (Day 6)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '19 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	20 Nov 2020 12:22:57
User entered '18 Nov 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '94'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:14:01

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 1 (Day 1)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:10:41
User entered '06 Nov 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Nov 2020 12:19:57
User entered '05 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:10:39
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:10:37
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:10:35
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:10:19
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:35:04
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:03
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:48
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:22:34
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:10:28
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:09:37
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:09:35
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:09:34
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

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Form: Symptom Log (7)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:09:32
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:09:30
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:09:29
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:09:18
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:09:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:09:15
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:09:13
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:09:22
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:37:02

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:34:58
User closed query 'Per source, started 10-NOV-2020. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:34:57
Query 'Per source, started 10-NOV-2020. Please review and update entries.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:58
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:22:34
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:08:13
User opened query 'Per source, started 10-NOV-2020. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:07:40
Query 'Per source, started 10-NOV-2020' canceled (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:07:22
User opened query 'Per source, started 10-NOV-2020' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:07:08
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02

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Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:34:55
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:34:53
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:05
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:22:34
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:08:11
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:08:05
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02



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Form: Symptom Log (7)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:34:52
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:34:50
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:12
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
User entered 'None (None)' reason for change: New Information	(b) (4)	
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:22:34
DataPoint Verified.	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4), (b) (6)	25 Nov 2020 00:08:22
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 00:08:09
	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:23
	(b) (4)	
	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:08:27
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	19 Nov 2020 20:37:23
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:37:02

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Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 2 (Day 2)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:39:40

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Form: Symptom Log (8)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:10:51
User entered '07 Nov 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Nov 2020 12:19:57
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:47:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:47:19
User entered '06 Nov 2020' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:39:40
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:39:40

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:10:53
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:39:40

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Form: Symptom Log (8)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:10:54
User entered missing code ND - Not Done; reason for change New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 20:47:19
User entered empty.	System	19 Nov 2020 20:39:40

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:10:56
User entered missing code ND - Not Done; reason for change New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:11:15
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:35:20
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:18
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:24:02
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
User entered 'None (None)' reason for change: New Information	(b) (4)	25 Nov 2020 03:23:49
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:13:47
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:11:19
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:11:21
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:11:25
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:11:49
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:11:53
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:11:55
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:11:57
User entered 'Mild (Mild)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40



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Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:12:00
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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Form: Symptom Log (8)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:12:07
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:12:28
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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Form: Symptom Log (8)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:12:30
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:35:25
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:23
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:24:17
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
User entered 'None (None)' reason for change: New Information	(b) (4)	25 Nov 2020 03:23:49
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 00:12:58
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:12:32
User entered 'Moderate (Moderate)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4)	19 Nov 2020 20:47:19
	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:35:28
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:26
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:24:24
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
User entered 'None (None)' reason for change: New Information	(b) (4)	
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
DataPoint Verified.	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4), (b) (6)	25 Nov 2020 00:13:13
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 00:13:01
	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	
	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:35:31
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:30
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:24:31
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
User entered 'None (None)' reason for change: New Information	(b) (4)	
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:23:49
DataPoint Verified.	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4), (b) (6)	25 Nov 2020 00:13:27
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 00:13:03
	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
	(b) (4)	
	Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:13:38
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:13:35
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:13:05
User entered 'None (None)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:39:40



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 3 (Day 3)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:52
User entered '08 Nov 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Nov 2020 12:19:57
User entered '07 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:49
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:47
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:45
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:30
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:35:44
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:42
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:33
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:25:23
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:17:43
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:17:41
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:19
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:17
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:15
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:10
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:08
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:04
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:03
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:17:01
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:16:59
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:16:57
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:35:49
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:47
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:47
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:25:23
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:16:52
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:15:29
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:35:52
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:50
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:54
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:25:23
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:16:45
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:15:55
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:35:54
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:35:53
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:01
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:25:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:25:23
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:16:43
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:16:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:47:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 4 (Day 4)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:19:56
User entered '09 Nov 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Nov 2020 12:19:57
User entered '08 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:01
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:04
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 20:52:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:05
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:09
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:36:06
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:36:04
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:59
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:26:50
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:13
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:18:53
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:18
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:20
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:22
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:24
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:26
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:30
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:32
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:33
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:35
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:37
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:36:12
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:36:11
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:27:08
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:26:50
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:39
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:19:10
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:36:15
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:36:14
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:27:16
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:26:50
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:42
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:19:36
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:36:18
User closed query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 04:36:17
Query 'Per source, started 10-NOV-2020. Please review and update entries. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:27:23
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:26:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 03:26:50
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:20:44
User opened query 'Per source, started 10-NOV-2020. Please review and update entries. ' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:19:38
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4)	19 Nov 2020 20:52:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:20:48
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:52:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 5 (Day 5)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '10 Nov 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Nov 2020 12:21:05
User entered '09 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:53:46

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 6 (Day 6)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '11 Nov 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Nov 2020 12:21:05
User entered '10 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 20:54:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:54:35



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 7 (Day 7)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '12 Nov 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Nov 2020 12:21:05
User entered '11 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 20:55:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:55:35

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 8 (Day 8)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '13 Nov 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Nov 2020 12:21:05
User entered '12 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '96' reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered missing code ND - Not Done.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Nov 2020 20:58:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '99.3' F reason for change: New Information	Jennifer Molstead (b) (4)	20 Nov 2020 19:44:15
User entered missing code ND - Not Done.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 20:58:20
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:58:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 15 (Day 15)'	(b) (4) Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '20 Nov 2020'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '94'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	23 Nov 2020 12:20:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 12:20:28

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 16 (Day 16)'	(b) (4) Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '21 Nov 2020'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '94'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	23 Nov 2020 14:44:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:29



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 17 (Day 17)'	(b) (4) Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '22 Nov 2020'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '92'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Nov 2020 14:44:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 18 (Day 18)'	(b) (4) Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '23 Nov 2020'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '0'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '92'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:34:28
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:20:06

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 19 (Day 19)'	(b) (4) Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '24 Nov 2020'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '94'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:36:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 20 (Day 20)'	(b) (4) Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '25 Nov 2020'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '95'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:37:56



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 21 (Day 21)'	(b) (4) Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '26 Nov 2020'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '93'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	27 Nov 2020 13:38:51

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 13:38:51

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 22 (Day 22)'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '27 Nov 2020'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '99'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 23 (Day 23)'	(b) (4) Traci Hull (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '28 Nov 2020'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User closed query 'Per ETRTR, Please confirm response and update if needed. If not done please ensure a PD is recorded.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 21:22:01
Query 'Per ETRTR, Please confirm response and update if needed. If not done please ensure a PD is recorded.' answered with 'SUBJECT STATED THAT HE FEELS FINE AND DOES NOT FEEL IT IS NECESSARY TO TAKE TEMPERATURE OR OXYGEN LEVEL BECAUSE "I AM FINE NOW".' (Site from CRA).	Traci Hull (b) (4) (b) (4)	04 Dec 2020 20:52:02
User opened query 'Per ETRTR, Please confirm response and update if needed. If not done please ensure a PD is recorded.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 21:52:13
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:15:53

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 24 (Day 24)'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '29 Nov 2020'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User closed query 'Per ETRTR, Please confirm response and update if needed. If not done please ensure a PD is recorded.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 21:22:09
Query 'Per ETRTR, Please confirm response and update if needed. If not done please ensure a PD is recorded.' answered with 'SUBJECT STATED THAT HE FEELS FINE AND DOES NOT FEEL IT IS NECESSARY TO TAKE TEMPERATURE OR OXYGEN LEVEL BECAUSE "I AM FINE NOW".' (Site from CRA).	Traci Hull (b) (4) (b) (4)	04 Dec 2020 20:54:08
User opened query 'Per ETRTR, Please confirm response and update if needed. If not done please ensure a PD is recorded.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 21:52:21
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Nov 2020 12:16:22



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 25 (Day 25)'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '30 Nov 2020'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '95'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	01 Dec 2020 13:02:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 26 (Day 26)'	(b) (4) Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '1 Dec 2020'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '90'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	02 Dec 2020 12:46:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '97.6' F	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 12:46:07

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 27 (Day 27)'	(b) (4) Traci Hull (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '2 Dec 2020'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '91'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Dec 2020 12:16:16

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 28 (Day 28)'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '3 Dec 2020'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '93'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	04 Dec 2020 12:32:38

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 12:32:38



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 29 (Day 29)'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '4 Dec 2020'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '93'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Dec 2020 17:23:47

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 30 (Day 30)'	(b) (4) Traci Hull (b) (4)	07 Dec 2020 13:08:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '5 Dec 2020'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '94'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:08:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 31 (Day 31)'	(b) (4) Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '6 Dec 2020'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '94'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 13:10:40

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 32 (Day 32)'	(b) (4) Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '7 Dec 2020'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '100'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	08 Dec 2020 13:06:41

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Dec 2020 13:06:41



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 33 (Day 33)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '8 Dec 2020'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '94'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:08:32

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 34 (Day 34)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '9 Dec 2020'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Dec 2020 13:09:10

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 35 (Day 35)'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '10 Dec 2020'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '94'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	11 Dec 2020 14:06:43

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '97.2' F	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 36 (Day 36)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '11 Dec 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '92'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Dec 2020 20:21:24

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.2' F	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:21:24



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 37 (Day 37)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '12 Dec 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '95'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.2' F	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:22:48

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 38 (Day 38)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '13 Dec 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '95'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered '98.1' F	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:16
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	19 Dec 2020 20:24:04

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Day 39 (Day 39)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23
	(b) (4)	

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Form: Symptom Log (39)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '14 Dec 2020'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '0'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '96'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
User entered '%'	System	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '36.8' C	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 17:27:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:23:56
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:00:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'None (None)'	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:22:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:28

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered '13 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:13:33

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:28

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:13:33

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:28

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:28
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 11:43:55
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 'updated' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:05:29
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	17 Nov 2020 14:13:33
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:13:33

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:28

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:28
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "17-NOV-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "13-NOV-2020" for Illness Visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:50:54
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "17-NOV-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "13-NOV-2020" for Illness Visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	19 Nov 2020 12:07:46
User entered '13 Nov 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	19 Nov 2020 12:07:39
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "17-NOV-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "13-NOV-2020" for Illness Visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 12:02:07
User entered '17 Nov 2020'	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:33

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:28

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:13:33

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:28

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:13:33



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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:28

[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)	02 May 2021 23:24:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:13:33

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:28

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:13:33

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:28

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:03:28
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:13:33

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:28

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:17
User entered '1'	System	17 Nov 2020 14:13:33

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Generated On: 09 Jun 2021 17:27:28

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

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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)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User closed query 'Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 09:29:34
Query 'Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. ' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	14 Apr 2021 19:22:26
User opened query 'Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 23:20:12
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User closed query 'Please verify date as symptom log notes 16NOV2020' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:44:47
Query 'Please verify date as symptom log notes 16NOV2020' answered with 'UPDATED' (Site from CRA).	Jennifer Molstead (b) (4)	23 Nov 2020 16:50:22
User entered '16 Nov 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 16:50:14
User opened query 'Please verify date as symptom log notes 16NOV2020' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 23:03:30
User entered '16 Oct 2020'	Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User closed query 'Per CDM RQ: Response noted. However there is no symptom log for 14DEC2020. Please confirm end date and update as required.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 08:15:50
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
Query 'Per CDM RQ: Response noted. However there is no symptom log for 14DEC2020. Please confirm end date and update as required.' answered with 'END DATE OF COVID IS THE 14DEC2020. I HAVE ADDED THE DATE TO THE SYMPTOMS LOG.' (Site from DM).	(b) (4) Tammy Kohn (b) (4)	26 Apr 2021 19:23:05
User opened query 'Per CDM RQ: Response noted. However there is no symptom log for 14DEC2020. Please confirm end date and update as required.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 17:40:56
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 92% on Day 36(11DEC2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 17:40:56
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:10:34
Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 92% on Day 36(11DEC2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4)	21 Apr 2021 16:49:49
User entered '14 Dec 2020' reason for change: Per Query Resolution	Traci Hull (b) (4)	21 Apr 2021 16:49:16
User entered '12 Dec 2020' reason for change: Per Query Resolution	Traci Hull (b) (4)	21 Apr 2021 16:46:14

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[End Date](#)

Audit	User	Time (GMT)
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 92% on Day 36(11DEC2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) Traci Hull (b) (4)	21 Apr 2021 12:22:02 14 Apr 2021 19:21:49
User entered '16 Nov 2020' reason for change: Per Query Resolution DataPoint Verified.	Traci Hull (b) (4) (b) (4), (b) (6)	14 Apr 2021 19:21:49 25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57



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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered '83' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	20 Nov 2020 19:39:30
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

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Generated On: 09 Jun 2021 17:27:28

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User closed query 'Per ETRTR, please confirm date and update if needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:01:21
Query 'Per ETRTR, please confirm date and update if needed.' answered with 'SUBJECT STATED THAT HE FEELS FINE AND DOES NOT FEEL IT IS NECESSARY TO TAKE TEMPERATURE OR OXYGEN LEVEL BECAUSE "I AM FINE NOW".' (Site from CRA).	Traci Hull (b) (4) (b) (4)	04 Dec 2020 20:58:39
User opened query 'Per ETRTR, please confirm date and update if needed.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 21:53:51
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered '16 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User closed query 'High-Flow Oxygen? Is marked YES but end date is missing. Please review and reconcile, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 09:30:50
Query 'High-Flow Oxygen? Is marked YES but end date is missing. Please review and reconcile, else clarify. ' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4) (b) (4)	14 Apr 2021 19:21:45
User opened query 'High-Flow Oxygen? Is marked YES but end date is missing. Please review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 23:21:14
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57



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[Evidence of Shock Requires Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57

US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:28

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:04:04
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 12:06:57



US3402194

Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:27:28

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:28
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:46:57
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	08 Dec 2020 23:34:34

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:28

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

**US3402194**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:27:28**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered '15 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:27:28

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:27:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 13:31:06
DataPoint Un-verified.	Jennifer Molstead (b) (4)	25 Nov 2020 03:28:36
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4) Jennifer Molstead (b) (4)	25 Nov 2020 03:28:36
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered 'Yes (Y)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	19 Nov 2020 12:09:26
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:27:28

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4)	25 Nov 2020 13:31:09
	(b) (4), (b) (6)	
User closed query 'Per source, subject did not take saliva kit to hospital. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 13:30:58
Query 'Per source, subject did not take saliva kit to hospital. Please review and update entries.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	25 Nov 2020 03:28:47
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	25 Nov 2020 03:28:36
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4)	25 Nov 2020 03:28:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User opened query 'Per source, subject did not take saliva kit to hospital. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 00:02:27
User entered '17 Nov 2020' reason for change: Per Query Resolution	Traci Hull (b) (4)	19 Nov 2020 12:09:26
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	16 Nov 2020 12:57:40
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:27:28

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40



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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:27:28

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

**US3402194**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:27:28**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:27:28

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:27:28

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

**US3402194**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:27:28**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:27:28

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:27:28

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

**US3402194**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:27:28**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40



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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:27:28

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:27:28

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

**US3402194**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:27:28**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:27:28

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

US3402194

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:27:28

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:24:39
DataPoint Un-verified.	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:50:18
User entered 'Yes (Y)' reason for change: Per Query Resolution	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:50:18
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:58:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 12:58:03
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:58:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 12:57:40
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:27:28

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:24:41
DataPoint Un-verified.	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:50:26
User entered '14 Dec 2020' reason for change: Per Query Resolution	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:50:26
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:02:30
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:40

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:53:53

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:34
User entered '13 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:53:53



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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:34
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:53:53

US3402194

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered 'SICKD1'	System	16 Nov 2020 12:53:53

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '13 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '11:37'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

**US3402194**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered '13 Nov 2020 11:37'	System	16 Nov 2020 12:55:33

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 13:33:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:33:47
Comment added 'correct as is.'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:56:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 12:55:33
User entered 'N/D' (non-conformant).	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33
DataPoint set to visible.	System	16 Nov 2020 12:53:53

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 13:33:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:33:47
Comment added 'correct as is'.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:56:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 12:55:33
User entered 'N/D' (non-conformant).	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33
DataPoint set to visible.	System	16 Nov 2020 12:53:53



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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '99.3' F	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '87'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered 'bpm'	System	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '14'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered 'breaths/min'	System	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '107'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33



US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered 'mmHg'	System	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:43
User entered '65'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered 'mmHg'	System	16 Nov 2020 12:55:33

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42

US3402194

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42

US3402194

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:54
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:56:52

US3402194

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:55:54
User entered '13 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:56:52

US3402194

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:28

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:56:00
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:23



US3402194

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:56:00
User entered '13 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 12:57:23

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:31:31
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:47:51

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:31:31
User entered '14 Dec 2020'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:47:51

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[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 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:31:31
User entered 'Clinic (Clinic)'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:47:51

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'SICKD28'	System	14 Dec 2020 18:47:51

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered '14 Dec 2020'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered '13:06'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:49



US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered '14 Dec 2020 13:06'	System	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered '160' cm	Abigail Wine (b) (4)	14 Dec 2020 18:49:49
DataPoint set to visible.	(b) (4) System	14 Dec 2020 18:47:51

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User closed query 'Per source weight was 99.7kg. Please review and update entries.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:19:52
Query 'Per source weight was 99.7kg. Please review and update entries.' answered with 'INFORMATION HAS BEEN CORRECTED.' (Site from CRA). DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:45:37
User entered '99.7' kg reason for change: Data Entry Error DataPoint Verified.	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:45:22
User opened query 'Per source weight was 99.7kg. Please review and update entries.' (Site from CRA). User entered '79' kg DataPoint set to visible.	(b) (4), (b) (6) Abigail Wine (b) (4) (b) (4) System	12 Feb 2021 17:37:26 12 Feb 2021 17:35:06 14 Dec 2020 18:49:49 14 Dec 2020 18:47:51

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered '36.8' C	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered 'Oral (Oral)'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered empty.	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered '81'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'bpm'	System	14 Dec 2020 18:49:49



US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered '15'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'breaths/min'	System	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered '120'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'mmHg'	System	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:37:26
User entered '79'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'mmHg'	System	14 Dec 2020 18:49:49

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40



US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:38:19
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:57

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:38:19
User entered '14 Dec 2020'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:49:57

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:28

[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 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:39:55
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	14 Dec 2020 18:50:06

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User closed query 'Per GCL query, please provide accession number.' (Site from CRA).	(b) (4)	26 Feb 2021 18:19:18
Query 'Per GCL query, please provide accession number.' answered with 'Swab is going out today 22DEC2020 AWB# 933677662443 ' (Site from CRA).	Tammy Kohn (b) (4)	15 Feb 2021 19:44:56
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 17:39:55
User opened query 'Per GCL query, please provide accession number.' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 17:39:53
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample 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)	24 Dec 2020 12:17:35
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample 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 will be sent' (Site from DM).	Jennifer Molstead (b) (4)	22 Dec 2020 11:47:22

US3402194

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:28

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample 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). User entered '14 Dec 2020'	(b) (4), (b) (6) [REDACTED] [REDACTED]	22 Dec 2020 10:21:50
	Abigail Wine (b) (4) [REDACTED]	14 Dec 2020 18:50:06

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:09:08

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '4 Feb 2021'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:09:08

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:09:08



US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 13:09:08

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:28

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '06 Jan 2021'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:28

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:10:47

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:28

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:10:51

**US3402194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:27:28**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
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 11:10:47

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:28

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '4 Feb 2021'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:28

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:28

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:10:51



US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:28

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:28

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:28

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '1'	System	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:28

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'I'	System	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered empty.	System	05 Feb 2021 13:17:15
DataPoint set to visible.	System	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15



US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered empty.	System	05 Feb 2021 13:17:15
DataPoint set to visible.	System	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '4 Feb 2021'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '15:20'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '4 Feb 2021 15:20'	System	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '36.6' C	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15



US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered empty.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '77'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:17:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'bpm'	System	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '22'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'breaths/min'	System	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '108'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'mmHg'	System	05 Feb 2021 13:17:15



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '65'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'mmHg'	System	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered empty.	System	05 Feb 2021 13:17:15
DataPoint set to visible.	System	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '4 Feb 2021'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15



US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '16:06'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '4 Feb 2021 16:06'	System	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '36.7' C	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered empty.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '74'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'bpm'	System	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '20'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:17:15



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'breaths/min'	System	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '113'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'mmHg'	System	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '70'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'mmHg'	System	05 Feb 2021 13:17:15

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:31

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Feb 2021 13:17:38
User entered '4 Feb 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:17:38
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Feb 2021 13:17:31
User entered '5 Feb 2021'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:17:31

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:55



US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered empty.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:55

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered empty.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:55

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'mRNA-1273'	System	05 Feb 2021 13:17:55
DataPoint set to visible.	System	05 Feb 2021 13:10:51

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '4 Feb 2021'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:55

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '15:46'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:55

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '4 Feb 2021 15:46'	System	05 Feb 2021 13:17:55

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:17:55

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'ONCE'	System	05 Feb 2021 13:17:55



US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 13:17:55

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:11:04

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '4 Feb 2021'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:11:04

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '14:55'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:11:04

**US3402194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '4 Feb 2021 14:55'	System	05 Feb 2021 13:11:04

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:11:16

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '4 Feb 2021'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:11:16

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '14:50'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:11:16



**US3402194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:27:28**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '4 Feb 2021 14:50'	System	05 Feb 2021 13:11:16

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:11:19

US3402194

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '1'	System	05 Feb 2021 13:11:19

US3402194

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	12 Feb 2021 13:22:30

US3402194

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '11 Feb 2021'	(b) (4) Traci Hull (b) (4)	12 Feb 2021 13:22:30

US3402194

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	12 Feb 2021 13:22:30

US3402194

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered empty.	(b) (4) Traci Hull (b) (4)	12 Feb 2021 13:22:30

US3402194

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	12 Feb 2021 13:22:17



**US3402194**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '1'	System	12 Feb 2021 13:22:17

US3402194

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '1'	System	12 Feb 2021 13:22:17
DataPoint set to visible.	System	12 Feb 2021 13:22:17

US3402194

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:01:25
	(b) (4)	

US3402194

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '2 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:01:25
	(b) (4)	

US3402194

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Clinic (Clinic)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:01:25

**US3402194**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'OLD29'	System	02 Mar 2021 20:01:25

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44



US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '2 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '12:11'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '2 Mar 2021 12:11'	System	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '36.5' C	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44
	(b) (4)	

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44
	(b) (4)	

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered empty.	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '74'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'bpm'	System	02 Mar 2021 20:02:44



US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '16'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'breaths/min'	System	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '125'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'mmHg'	System	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '65'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'mmHg'	System	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44
	(b) (4)	



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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '2 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44
	(b) (4)	

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '13:16'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '2 Mar 2021 13:16'	System	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '36.3' C	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44
	(b) (4)	

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered empty.	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '71'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'bpm'	System	02 Mar 2021 20:02:44



US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '16'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'breaths/min'	System	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '124'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'mmHg'	System	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:09
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Mar 2021 20:02:58
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	02 Mar 2021 20:02:58
User entered '73' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	02 Mar 2021 20:02:58
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Mar 2021 20:02:44
User entered '43'	Tammy Kohn (b) (4) (b) (4)	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'mmHg'	System	02 Mar 2021 20:02:44

US3402194

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:03:07

US3402194

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '2 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:03:07
	(b) (4)	



US3402194

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:03:32

US3402194

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered empty.	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:03:32

US3402194

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered empty.	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:03:32
	(b) (4)	

US3402194

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'mRNA-1273'	System	02 Mar 2021 20:03:32
DataPoint set to visible.	System	12 Feb 2021 13:22:17

US3402194

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '2 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:03:32

US3402194

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered '12:30'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:03:32

**US3402194**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:28**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '2 Mar 2021 12:30'	System	02 Mar 2021 20:03:32

US3402194

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:03:32



US3402194

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'ONCE'	System	02 Mar 2021 20:03:32

US3402194

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:28

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 20:03:32

US3402194

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	02 Mar 2021 20:03:44

US3402194

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered '1'	System	02 Mar 2021 20:03:44

US3402194

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 14:24:08

**US3402194**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:28**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered '09 Mar 2021'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 14:24:08

**US3402194**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 14:24:08

US3402194

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Mar 2021 14:24:08



US3402194

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:28
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 14:24:12

**US3402194**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:10:55
User entered 'I'	System	09 Mar 2021 14:24:12

US3402194

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	30 Mar 2021 18:15:28
	(b) (4)	

US3402194

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered '30 Mar 2021'	Traci Hull (b) (4)	30 Mar 2021 18:15:28
	(b) (4)	

**US3402194**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:28**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	30 Mar 2021 18:15:28
	(b) (4)	

**US3402194**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:28**

[Folder OID](#)

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Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 18:15:28

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US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	30 Mar 2021 18:15:42
	(b) (4)	

US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:42
	(b) (4)	



US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:42
	(b) (4)	

**US3402194**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:28**

[Vital Signs Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:15:42

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US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:42
	(b) (4)	

US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:42
	(b) (4)	

US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:42
	(b) (4)	

US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:42
	(b) (4)	

**US3402194**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:28**

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:15:42

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US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:42
	(b) (4)	



**US3402194**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:28**

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:15:42

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US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:42
	(b) (4)	

**US3402194**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:28**

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:15:42

---

US3402194

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:42
	(b) (4)	

**US3402194**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:28**

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:15:42

---

US3402194

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	30 Mar 2021 18:15:48
	(b) (4)	

US3402194

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 18:15:48
	(b) (4)	

**US3402194**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	30 Mar 2021 18:16:16
	(b) (4)	



**US3402194**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

*Collection date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered '30 Mar 2021'	Traci Hull (b) (4)	30 Mar 2021 18:16:16
	(b) (4)	

**US3402194**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
	(b) (4)	
User entered '12:37'	Traci Hull (b) (4)	30 Mar 2021 18:16:16
	(b) (4)	

**US3402194**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:28**

[Collection date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '30 Mar 2021 12:37'	System	30 Mar 2021 18:16:16

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US3402194

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:27:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:45:14
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:19
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	17 Nov 2020 14:13:52
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:42:16

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4)	24 Nov 2020 23:52:11
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:06
User entered 'USA-US059-2020-mRNA-1273-P301000018'	System	18 Nov 2020 15:53:59
User entered 'New'	(b) (4), (b) (6)	18 Nov 2020 15:53:59

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4)	22 Jan 2021 20:58:55
	(b) (4), (b) (6)	
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)	07 Dec 2020 13:48:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 13:48:44
	(b) (4)	
Data point term sent to Coder	System	07 Dec 2020 13:48:14
DataPoint Un-verified.	Jennifer Molstead (b) (4)	07 Dec 2020 13:47:30
	(b) (4)	
Coding entries removed.	Jennifer Molstead (b) (4)	07 Dec 2020 13:47:30
	(b) (4)	
User entered 'SARS COVID-19' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Dec 2020 13:47:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
	(b) (4), (b) (6)	
User closed query 'Please consider updating term to COVID-19' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:37:13
	(b) (4), (b) (6)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 20:13:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 20:13:02
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 20:12:00
Query 'Please consider updating term to COVID-19' answered with 'UPDATED' (Site from CRA).	Traci Hull (b) (4)	23 Nov 2020 20:11:51
	(b) (4)	
Coding entries removed.	Traci Hull (b) (4)	23 Nov 2020 20:11:43
	(b) (4)	
User entered 'COVID-19' reason for change: Per Query Resolution	Traci Hull (b) (4)	23 Nov 2020 20:11:43
	(b) (4)	
User opened query 'Please consider updating term to COVID-19' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 18:13:44
	(b) (4), (b) (6)	
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)	17 Nov 2020 14:17:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 14:17:47
	(b) (4)	
Data point term sent to Coder	System	17 Nov 2020 14:16:28

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Sars Covid-19'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:59:34
User closed query 'PV Query: Please clarify start date of 05 Nov 2020 as start date should be date of onset of symptoms or date of positive test, whichever occurred first. Per symptom log, date of onset of symptoms is 06 Nov.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 17:41:05
Query 'PV Query: Please clarify start date of 05 Nov 2020 as start date should be date of onset of symptoms or date of positive test, whichever occurred first. Per symptom log, date of onset of symptoms is 06 Nov.' answered with 'UODATED' (Site from Safety).	Traci Hull (b) (4) (b) (4)	01 Dec 2020 15:00:19
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	01 Dec 2020 15:00:06
User entered '06 Nov 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	01 Dec 2020 15:00:06
User opened query 'PV Query: Please clarify start date of 05 Nov 2020 as start date should be date of onset of symptoms or date of positive test, whichever occurred first. Per symptom log, date of onset of symptoms is 06 Nov.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 23:36:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '05 Nov 2020' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 20:31:57
User entered '03 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

**US3402194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:28**

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:24:40
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	07 Dec 2020 14:23:58
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:23:58
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:23:58
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	07 Dec 2020 14:23:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:24:43
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	07 Dec 2020 14:23:40
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	07 Dec 2020 14:23:40
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:23:40
User entered '26 Nov 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:23:40
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	07 Dec 2020 13:47:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

**US3402194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:28**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 14:46:42
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:55:58
User entered empty.	System	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
User closed query 'PV Query: As event resulted in hospitalization, please consider upgrading intensity to grade 4. If not, please further clarify.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:41:19
Query 'PV Query: As event resulted in hospitalization, please consider upgrading intensity to grade 4. If not, please further clarify.' answered with 'CORRECT AS IS' (Site from Safety).	Traci Hull (b) (4) (b) (4)	01 Dec 2020 15:00:53
User opened query 'PV Query: As event resulted in hospitalization, please consider upgrading intensity to grade 4. If not, please further clarify.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 23:37:14
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 13:18:50
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'PATIENT STILL IN HOSPITAL' (Site from System).	Traci Hull (b) (4) (b) (4)	23 Nov 2020 20:13:48
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Nov 2020 20:13:24
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 04:07:23
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'not available at this time' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:51
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	17 Nov 2020 14:16:23
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '16 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4)	12 Feb 2021 17:24:46
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 17:40:59
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'UPDATED' (Site from Safety).	Traci Hull (b) (4)	01 Dec 2020 15:01:05
DataPoint Un-verified.	(b) (4)	
	Traci Hull (b) (4)	01 Dec 2020 15:00:06
User entered '26 Nov 2020' reason for change: Per Query Resolution	(b) (4)	
	Traci Hull (b) (4)	01 Dec 2020 15:00:06
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 23:36:00
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 15:16:04
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'STILL IN HOSPITAL' (Site from Safety).	Traci Hull (b) (4)	23 Nov 2020 20:13:01
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:56:25
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23
	(b) (4)	



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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User closed query 'Per CDM RQ: Response noted. However, if subject is currently not admitted to ICU, please update field. If ICU admission changes, please update field appropriately. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:48:18
Query 'Per CDM RQ: Response noted. However, if subject is currently not admitted to ICU, please update field. If ICU admission changes, please update field appropriately. ' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	23 Nov 2020 20:13:57
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	23 Nov 2020 20:13:24
User opened query 'Per CDM RQ: Response noted. However, if subject is currently not admitted to ICU, please update field. If ICU admission changes, please update field appropriately. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:45:38
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 13:44:53
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'not available at this time' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:53
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	17 Nov 2020 14:16:23
User entered 'Unknown (UNK)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23



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None

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0' reason for change: New Information	Traci Hull (b) (4)	23 Nov 2020 20:14:50
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	17 Nov 2020 16:51:19
User entered '1' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Nov 2020 16:51:19
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	17 Nov 2020 14:16:23
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '1' reason for change: New Information	Traci Hull (b) (4)	23 Nov 2020 20:14:50
User entered '0'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:29:40
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 13:34:25
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:24:06
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 13:47:30
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 13:47:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	23 Nov 2020 20:14:50
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:56:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Molstead (b) (4) (b) (4)	17 Nov 2020 14:16:23

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:59:12
DataPoint Un-verified.	Jennifer Molstead (b) (4)	07 Dec 2020 13:47:30
User entered 'While subject was discharged 26Nov2020 he was sent home with supplemental oxygen of 1 liter to use as needed.' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	07 Dec 2020 13:47:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:52:11
User entered empty.	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:59:14
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 13:34:30
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 13:34:29
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 13:34:27
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Updated and faxed' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 15:27:09
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:24:20
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:24:15

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject phoned office 13nov2020 that he was having covid like symptoms which had started 06nov2020. At that point he had diarrhea, which he thought was a gastrointestinal issue not covid related. Upon receiving the phone call a home visit was preformed by 2 coordinators, and the physician spoke to the subject by telephone. Subject was followed per protocol   for the convalescent days. SUBJECT PRESENTED TO THE EMERGENCY ROOM 16NOV2020 WITH SHORTNESS OF BREATH. A chest x ray was performed which showed Bilateral Air Space Disease Concerning for Pneumonia. Subject also had Elevated lactate of 1181, D-Dimer 216, CRP 20.3, Ferritin 912. Subject was started on Remdesiver, Convalescent Plasma, Dexamethasone, Thiamine, Lovenox, Oxygen, and Melatonin. oncc subject was started on the 6 Liters of Oxygen he stated feeling much better and that his symptoms were resolving. Subject completed a 5 day course of Remdesiver, and 10 days of Dexamethasone. Due to subject not keeping a stable Oxygen Saturation he was sent home on 1 liter of oxygen.' reason for change: Data Entry Error DataPoint Un-verified.	Jennifer Molstead (b) (4)	(b) (4) 07 Dec 2020 14:23:40
User entered 'subject presented to the emergency room 16nov2020 with shortness of breath.' reason for change: Data Entry Error DataPoint Verified.	Jennifer Molstead (b) (4)	(b) (4) 07 Dec 2020 13:47:30
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 23:52:11
	(b) (4), (b) (6)	20 Nov 2020 19:57:28

US3402194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:28

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:57:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:56:50
User entered 'Subject admitted 16Nov2020 no records available yet.'	Jennifer Molstead (b) (4)	17 Nov 2020 14:16:23



**US3402194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:28**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 14:16:23

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**US3402194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:28**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 14:16:23

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**US3402194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:28**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 14:16:23

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US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:27:28

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:45:14
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:40:55
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:42:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: ADMELOG - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 14:57:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 14:57:06
Data point term sent to Coder	System	03 Aug 2020 14:47:23
Data point term sent to Coder	System	03 Aug 2020 14:45:22
User entered 'admelog u-100'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'type 1 diabetes'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4)	24 Nov 2020 23:47:21
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review and provide the dose range (e.g., 5-10 IU) instead of stating 'SLIDING SCALE'. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:41:09
Query 'Per DM CLR: Please review and provide the dose range (e.g., 5-10 IU) instead of stating 'SLIDING SCALE'. Update as appropriate. ' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4)	08 Oct 2020 14:33:33
	(b) (4)	
User entered '100' reason for change: New Information	Traci Hull (b) (4)	08 Oct 2020 14:33:25
	(b) (4)	
User opened query 'Per DM CLR: Please review and provide the dose range (e.g., 5-10 IU) instead of stating 'SLIDING SCALE'. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:02:28
User entered 'sliding scale'	Traci Hull (b) (4)	03 Aug 2020 14:45:19
	(b) (4)	



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'UNITS' reason for change: New Information	Traci Hull (b) (4) (b) (4)	08 Oct 2020 14:33:25
User entered 'sliding scale'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 14:46:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 14:46:44
User entered 'three times daily (TID)' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:44
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 14:45:19
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 14:46:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 14:46:44
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:44
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 14:45:19
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed 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).	(b) (4), (b) (6)	04 Aug 2020 00:06:43
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.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4)	03 Aug 2020 14:46:36
	(b) (4)	
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	03 Aug 2020 14:45:19
User entered 'un UNK 1979'	Traci Hull (b) (4)	03 Aug 2020 14:45:19
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:45:19

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:27:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 Aug 2020 14:46:44
User entered empty.	System	03 Aug 2020 14:45:19

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:46:44
User entered empty.	System	03 Aug 2020 14:45:19

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 14:46:44
User entered empty.	System	03 Aug 2020 14:45:19

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Nov 2020 19:37:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Nov 2020 19:37:48
Data point term sent to Coder	System	18 Nov 2020 19:36:29
Coding entries removed.	Abigail Wine (b) (4)	18 Nov 2020 19:36:10
	(b) (4)	
User entered 'BRILINTA' reason for change: Per Query Resolution	Abigail Wine (b) (4)	18 Nov 2020 19:36:10
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Aug 2020 21:09:04
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Aug 2020 21:09:04
	(b) (4)	
Data point term sent to Coder	System	03 Aug 2020 14:46:23
User entered 'brlinta'	Traci Hull (b) (4)	03 Aug 2020 14:46:00
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'peripheral vascular disease'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '90'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed 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).	(b) (4), (b) (6)	04 Aug 2020 00:06:47
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.'	Traci Hull (b) (4)	03 Aug 2020 14:46:09
answered with 'ongoing' (Site from System).	(b) (4)	
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	03 Aug 2020 14:46:00
User entered 'un UNK 2018'	Traci Hull (b) (4)	03 Aug 2020 14:46:00
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:46:00

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:28**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:46:00

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:46:00

---

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 14:46:00

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US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 14:57:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 14:57:07
Data point term sent to Coder	System	03 Aug 2020 14:48:24
User entered 'atorvastatin'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'coronary artery disease'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '20'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed 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).	(b) (4), (b) (6)	04 Aug 2020 00:06:51
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.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:51
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	03 Aug 2020 14:47:40
User entered 'un May 2017'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:47:40

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:28**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:47:40

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:47:40

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 14:47:40

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US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
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)	04 Aug 2020 14:32:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:32:14
Data point term sent to Coder	System	03 Aug 2020 14:49:24
User entered 'lisinopril'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'coronary artery disease'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '2.5'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed 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).	(b) (4), (b) (6)	04 Aug 2020 00:06:56
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. answered with 'ongoing' (Site from System).	Traci Hull (b) (4)	03 Aug 2020 14:48:34
	(b) (4)	
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	03 Aug 2020 14:48:27
User entered 'un May 2017'	Traci Hull (b) (4)	03 Aug 2020 14:48:27
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 14:48:27

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:27:28**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:48:27

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 14:48:27

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 14:48:27

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US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:00:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:00:49
Data point term sent to Coder	System	18 Nov 2020 18:58:23
User entered 'albuterol'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '90'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'ug (ug)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'as needed (PRN)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 05:05:30
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 'Subject is still using this medication if needed.' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	22 Jan 2021 21:35:17
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)	21 Jan 2021 12:33:16
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 18:57:50

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:27:28**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 18:57:50

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 18:57:50

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 18:57:50

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US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:04:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:04:55
Data point term sent to Coder	System	18 Nov 2020 19:03:34
User entered 'dexamethasone'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '6'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:08:27
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:05:46
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 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:23:10
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:22:58
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:22:58
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)	21 Jan 2021 12:33:34
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:08:28
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 12:22:58
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 12:22:58
DataPoint Verified.	Tammy Kohn (b) (4)	24 Nov 2020 23:47:21
User entered empty.	(b) (4)	24 Nov 2020 23:47:21
	Abigail Wine (b) (4)	18 Nov 2020 19:03:24
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User entered '1'	System	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User entered '1'	System	18 Nov 2020 19:03:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:00
User entered '804 (804)'	System	18 Nov 2020 19:03:24



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 19:05:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 19:05:48
Data point term sent to Coder	System	18 Nov 2020 19:04:35
User entered 'acetaminophen'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '650'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'every 4 hours'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:08:36
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:06:12
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 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:30:06
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:23:52
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:23:52
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)	21 Jan 2021 12:33:49
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:08:38
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 12:23:52
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 12:23:52
DataPoint Verified.	Tammy Kohn (b) (4)	24 Nov 2020 23:47:21
User entered empty.	(b) (4)	24 Nov 2020 23:47:21
	Abigail Wine (b) (4)	18 Nov 2020 19:04:26
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User entered empty.	System	18 Nov 2020 19:04:26



**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User entered empty.	System	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:04
User entered empty.	System	18 Nov 2020 19:04:26

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:08:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 06:46:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 06:46:03
Data point term sent to Coder	System	23 Jan 2021 12:36:24
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:36:00
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:36:00
User entered 'DEXTROSE (D50W solution)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:36:00
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:04:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:04:59
Data point term sent to Coder	System	18 Nov 2020 19:05:37
User entered 'dextrose'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 08:58:23
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'THIS MEDICATION WAS GIVEN TO PATIENT WHILE IN THE HOSPITAL ALONG WITH THE OTHER MEDICATIONS LISTED AS A TREATMENT FOR SARS-COV-2. ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:54:28
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:34:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:08:46
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of the volume tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	Melita Rebello (2403 - melita_r2)	25 Jan 2021 05:17:51
Query 'Per DM CLR: Please provide the actual dose for this medication instead of the volume tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'THE ENTIRE IV BAG WAS DISPENCED WHICH WOULD BE THE ENTIRE 50ML OF MEDICATION. ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:37:47
User entered '50' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:37:04
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:36:00
User entered '500' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 12:36:00
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of the volume tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:38:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '50'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:08:48
User entered 'mL (mL)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Jan 2021 12:37:04
DataPoint Un-verified.	(b) (4)	
	Tammy Kohn (b) (4)	23 Jan 2021 12:36:00
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	23 Jan 2021 12:36:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mL (mL)'	Abigail Wine (b) (4)	18 Nov 2020 19:05:09
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once (ONCE)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User entered empty.	System	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User entered empty.	System	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:09
User entered empty.	System	18 Nov 2020 19:05:09

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Jan 2021 20:43:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Jan 2021 20:43:53
Data point term sent to Coder	System	23 Jan 2021 13:48:26
Coding entries removed.	Tammy Kohn (b) (4)	23 Jan 2021 13:47:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 04:09:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 04:09:59
Data point term sent to Coder	System	18 Nov 2020 19:06:41
User entered 'furosemide'	Abigail Wine (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:11:05
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:07:47
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'DATA UPDATED ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:50:56
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:47:45
User entered 'FLUID RETENSION DUE TO SARS-COV-2' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:47:45
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:39:51
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '20'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:11:12
User closed query ' Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:07:52
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 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:56:00
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:55:45
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:55:45
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)	21 Jan 2021 12:40:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:11:15
User entered '26 Nov 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Jan 2021 13:56:38
DataPoint Un-verified.	(b) (4)	23 Jan 2021 13:55:45
User entered '14 Dec 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Jan 2021 13:55:45
DataPoint Verified.	(b) (4)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:06:12
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User entered '1'	System	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User entered '1'	System	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:15
User entered '804 (804)'	System	18 Nov 2020 19:06:12

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:01:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:01:49
Data point term sent to Coder	System	18 Nov 2020 19:24:12
User entered 'ascorbic acid'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '1000'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:50:08
User closed query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 13:28:48
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	01 Dec 2020 20:26:57
Query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:22:25
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	01 Dec 2020 20:22:14
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:22:14
User entered 'three times daily (TID)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:22:14
User opened query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:35:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:50:01
DataPoint Un-verified.	Traci Hull (b) (4)	01 Dec 2020 20:26:57
User entered empty; reason for change Per Query Resolution	(b) (4) Traci Hull (b) (4)	01 Dec 2020 20:26:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'every 8 hours'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '17 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:23:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 19:23:49
User entered 'No (N)' reason for change: Per Query Resolution	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:49
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:23:43
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User entered '3'	System	01 Dec 2020 20:22:14
User entered empty.	System	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User entered '1'	System	01 Dec 2020 20:22:14
User entered empty.	System	18 Nov 2020 19:23:43

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:18
User entered '804 (804)'	System	01 Dec 2020 20:22:14
User entered empty.	System	18 Nov 2020 19:23:43



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:02:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:02:49
Data point term sent to Coder	System	18 Nov 2020 19:25:17
User entered 'aspirin'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:50:32
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 09:47:20
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 13:43:41
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 13:43:35
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 13:43:35
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:15:00
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '81'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:13:44
User closed query 'Per DM CLR: After reviewing if the prophylaxis indication should be changed, please confirm 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)	25 Jan 2021 05:09:01
Query 'Per DM CLR: After reviewing if the prophylaxis indication should be changed, please confirm 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 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:57:43
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:57:36
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:57:36
User opened query 'Per DM CLR: After reviewing if the prophylaxis indication should be changed, please confirm 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)	21 Jan 2021 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:13:46
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 13:57:36
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 13:57:36
DataPoint Verified.	Tammy Kohn (b) (4)	23 Jan 2021 13:57:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:24:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User entered '1'	System	18 Nov 2020 19:24:35



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User entered '1'	System	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:23
User entered '804 (804)'	System	18 Nov 2020 19:24:35

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: GLUCOSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Jan 2021 20:44:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Jan 2021 20:44:55
Data point term sent to Coder	System	23 Jan 2021 13:58:27
Coding entries removed.	Tammy Kohn (b) (4)	23 Jan 2021 13:58:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: GLUCOSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 04:25:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 04:25:53
Data point term sent to Coder	System	18 Nov 2020 19:26:17
User entered 'glucose chewable tablet'	Abigail Wine (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:01
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:09:44
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:58:27
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:58:23
User entered 'TYPE 2 DIABETIS WITH SARS-COV-2' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:58:23
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:41:49
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:05
User closed query 'Per CDM re-query: Response indicates 'data updated'; However there is no obvious update made. Please review and update the dose as it is not the standard dose for this medication per previous query. Please update else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 08:58:54
Query 'Per CDM re-query: Response indicates 'data updated'; However there is no obvious update made. Please review and update the dose as it is not the standard dose for this medication per previous query. Please update else clarify in query response.' answered with '4 GRAM TABS ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 20:20:06
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 20:19:51
User entered '4' reason for change: Data Entry Error	Tammy Kohn (b) (4)	25 Jan 2021 20:19:51
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 05:11:20
User opened query 'Per CDM re-query: Response indicates 'data updated'; However there is no obvious update made. Please review and update the dose as it is not the standard dose for this medication per previous query. Please update else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:11:18
Query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:58:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 12:42:01
User entered '12'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'g (g)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'as needed (PRN)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Oral (ORAL)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:08
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:11:51
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 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:58:34
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:58:23
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 13:58:23
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)	21 Jan 2021 12:45:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:11
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 13:58:23
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 13:58:23
DataPoint Verified.	Tammy Kohn (b) (4)	23 Jan 2021 13:58:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:25:24
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User entered empty.	System	18 Nov 2020 19:25:24

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User entered empty.	System	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:27
User entered empty.	System	18 Nov 2020 19:25:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:11:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:11:01
Data point term sent to Coder	System	18 Nov 2020 19:27:18
User entered 'heparin'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '40'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'units/kg'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:39
User closed query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 13:31:41
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:28:03
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:27:49
User entered 'four times daily (QID)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:27:49
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:35:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:40
DataPoint Un-verified.	Traci Hull (b) (4)	01 Dec 2020 20:27:49
User entered empty; reason for change Per Query Resolution	(b) (4) Traci Hull (b) (4)	01 Dec 2020 20:27:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'every 6 hours'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:45
DataPoint Un-verified.	Jennifer Molstead (b) (4)	07 Dec 2020 14:25:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Jennifer Molstead (b) (4)	07 Dec 2020 14:25:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:47
DataPoint Un-verified.	Jennifer Molstead (b) (4)	07 Dec 2020 14:25:11
User entered '17 Nov 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Jennifer Molstead (b) (4)	07 Dec 2020 14:25:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:27:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User entered '4'	System	01 Dec 2020 20:27:49
User entered empty.	System	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User entered '1'	System	01 Dec 2020 20:27:49
User entered empty.	System	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:32
User entered '804 (804)'	System	01 Dec 2020 20:27:49
User entered empty.	System	18 Nov 2020 19:27:06

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE WATER - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Jan 2021 06:45:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Jan 2021 06:45:03
User closed query 'Per DM CLR: After reviewing the start/stop date of this medication, please confirm the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:13:19
Query 'Per DM CLR: After reviewing the start/stop date of this medication, please confirm the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4)	23 Jan 2021 14:23:45
Data point term sent to Coder	System	23 Jan 2021 14:23:29
Coding entries removed.	Tammy Kohn (b) (4)	23 Jan 2021 14:23:15
User opened query 'Per DM CLR: After reviewing the start/stop date of this medication, please confirm the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:46:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE WATER - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:49:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:49:17
Data point term sent to Coder	System	18 Nov 2020 19:29:20
User entered 'D5W'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:22
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 14:23:15
User entered 'FLUID LOSS DUE TO SARS-COV-2'	(b) (4)	23 Jan 2021 14:23:15
reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Jan 2021 14:23:15
DataPoint Verified.	(b) (4)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	(b) (4), (b) (6)	24 Nov 2020 23:47:21
	Abigail Wine (b) (4)	18 Nov 2020 19:28:47
	(b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0-24'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'units/kg/hour'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:55
User closed query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 13:32:05
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:28:39
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:28:28
User entered 'four times daily (QID)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:28:28
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:35:35
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:51:57
DataPoint Un-verified.	Traci Hull (b) (4)	01 Dec 2020 20:28:28
User entered empty; reason for change Per Query Resolution	(b) (4) Traci Hull (b) (4)	01 Dec 2020 20:28:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'every 6 hours'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med DEXTROSE, # 08 / (Start date 16NOV2020 - Stop date 16NOV2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 05:13:38
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med DEXTROSE, # 08 / (Start date 16NOV2020 - Stop date 16NOV2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:23:49
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med DEXTROSE, # 08 / (Start date 16NOV2020 - Stop date 16NOV2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:46:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:27
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 14:23:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 14:23:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:28
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 14:23:36
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 14:23:36
DataPoint Verified.	Tammy Kohn (b) (4)	24 Nov 2020 23:47:21
User entered empty.	(b) (4) Abigail Wine (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User entered '4'	System	01 Dec 2020 20:28:28
User entered empty.	System	18 Nov 2020 19:28:47



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User entered '1'	System	01 Dec 2020 20:28:28
User entered empty.	System	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:36
User entered '804 (804)'	System	01 Dec 2020 20:28:28
User entered empty.	System	18 Nov 2020 19:28:47

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
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 DIABETES TYPE 1 should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:48:22
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 DIABETES TYPE 1 should be recorded, and update con med indication or provide clarification. ' answered with 'PATIENT'S DIABETES WAS NO LONGER CONTROLLED WITH THE MEDICATION THEY WERE ON. THE PHYSICIAN SWITCHED THEIR MEDICATION TO SEE IF THIS WORKS BETTER. ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 13:56:35
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 DIABETES TYPE 1 should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:15:27
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:57:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:57:02
Data point term sent to Coder	System	18 Nov 2020 19:32:23
User entered 'insulin glargine'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'diabetes type 1'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '30'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'units'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'three times daily (TID)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Subcutaneous (SUBCUTANEOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:31:25

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:27:28**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '3'	System	18 Nov 2020 19:31:25

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:31:25

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 19:31:25

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US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
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 DIABETES TYPE 1 should be recorded, and update con med indication or provide clarification. ' (Site from DM). 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 DIABETES TYPE 1 should be recorded, and update con med indication or provide clarification. ' answered with 'PATIENT'S DIABETES WAS NO LONGER CONTROLLED WITH THE MEDICATION THEY WERE ON. THE PHYSICIAN SWITCHED THEIR MEDICATION TO SEE IF THIS WORKS BETTER' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:48:11
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 DIABETES TYPE 1 should be recorded, and update con med indication or provide clarification. ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 13:56:43
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 05:17:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:57:02
Data point term sent to Coder	System	18 Nov 2020 19:32:25
User entered 'insulin lispro'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'diabetes type 1'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '2-6'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'units'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'three times daily (TID)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Subcutaneous (SUBCUTANEOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:32:18

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:27:28**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '3'	System	18 Nov 2020 19:32:18

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 19:32:18

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**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 19:32:18

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US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:41:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:41:53
Data point term sent to Coder	System	18 Nov 2020 19:33:26
User entered 'remdesivir'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '100'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'once daily (QD)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '18 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:44
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:15:19
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 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:29:48
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:29:34
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:29:34
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)	21 Jan 2021 13:14:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:46
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	23 Jan 2021 14:29:34
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	23 Jan 2021 14:29:30
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 14:29:30
User entered '18 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 14:29:30
DataPoint Verified.	Tammy Kohn (b) (4)	23 Jan 2021 14:29:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:33:23
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:33:23

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:27:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User entered '1'	System	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User entered '1'	System	18 Nov 2020 19:33:23

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:44
User entered '804 (804)'	System	18 Nov 2020 19:33:23



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:07:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:07:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:39:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:39:56
Data point term sent to Coder	System	18 Nov 2020 19:34:28
User entered 'sodium chloride infusion'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0.9'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '%'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'as needed (PRN)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:55
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:15:28
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 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:30:34
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:30:30
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:30:30
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)	21 Jan 2021 13:14:44
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:14:56
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 14:30:30
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 14:30:30
DataPoint Verified.	Tammy Kohn (b) (4)	23 Jan 2021 14:30:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4)	18 Nov 2020 19:34:24
	(b) (4)	

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:34:24

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:27:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User entered empty.	System	18 Nov 2020 19:34:24



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User entered empty.	System	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:50
User entered empty.	System	18 Nov 2020 19:34:24

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:52:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:52:59
Data point term sent to Coder	System	18 Nov 2020 19:35:29
User entered 'thiamine'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'SARS-CoV-2'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '100'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:52:17
User closed query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please confirm if the frequency can be updated to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:23:58
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please confirm if the frequency can be updated to the available equivalent rather than Other. Thank you.' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:29:42
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:29:17
User entered 'three times daily (TID)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:29:17
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please confirm if the frequency can be updated to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:36:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:52:19
DataPoint Un-verified.	Traci Hull (b) (4)	01 Dec 2020 20:29:17
User entered empty; reason for change Per Query Resolution	(b) (4) Traci Hull (b) (4)	01 Dec 2020 20:29:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'every 8 hours'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Intravenous (INTRAVENOUS)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '17 Nov 2020'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:15:03
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:15:36
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 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:30:54
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:30:50
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:30:50
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)	21 Jan 2021 13:15:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:15:04
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 14:30:50
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 14:30:50
DataPoint Verified.	Tammy Kohn (b) (4)	24 Nov 2020 23:47:21
User entered empty.	(b) (4) Abigail Wine (b) (4)	18 Nov 2020 19:35:02



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User entered '3'	System	01 Dec 2020 20:29:17
User entered empty.	System	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User entered '1'	System	01 Dec 2020 20:29:17
User entered empty.	System	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User entered '804 (804)'	System	01 Dec 2020 20:29:17
User entered empty.	System	18 Nov 2020 19:35:02

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:41:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:41:59
Data point term sent to Coder	System	19 Nov 2020 13:31:12
User entered 'Oxygen'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Sars Covid 19'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of the total volume. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 05:16:28
Query 'Per DM CLR: Please provide the actual dose for this medication instead of the total volume. Update the Dose and Dose Unit fields as appropriate. ' answered with 'SUBJECT WAS ON 6 LITERS OF OXYGEN AT A TIME ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:31:58
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of the total volume. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 13:16:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '6'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Liters'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'continuous'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '16 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:15:17
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:15:56
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 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:32:15
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:32:10
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:32:10
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)	21 Jan 2021 13:16:26
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:15:21
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Jan 2021 14:32:10
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 14:32:10
DataPoint Verified.	Tammy Kohn (b) (4)	24 Nov 2020 23:47:21
User entered empty.	(b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:21
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User entered empty.	System	19 Nov 2020 13:30:29

**US3402194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:27:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User entered empty.	System	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:18
User entered empty.	System	19 Nov 2020 13:30:29

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
User closed query 'Per hospital admission records, Heparin was prescribed and not Lovenox. Please review and update entries.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:21:40
Query 'Per hospital admission records, Heparin was prescribed and not Lovenox. Please review and update entries.' answered with 'SUBJECT WAS SWITCHED FROM HEPARIN TO LOVENOX ON 17 NOV 2020' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 14:40:46
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 20:58:41
User opened query 'Per hospital admission records, Heparin was prescribed and not Lovenox. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 20:58:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 01:34:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 01:34:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LOVENOX [LEVOFLOXACIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 01:26:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 01:26:49
Data point term sent to Coder	System	07 Dec 2020 14:29:33
User entered 'Lovenox'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered 'Sars Covid-19'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered 'mg/kg'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45



US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered '17 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered '26 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:58:41
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User entered '2'	System	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User entered '1'	System	07 Dec 2020 14:28:45

US3402194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:27:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:21
User entered '804 (804)'	System	07 Dec 2020 14:28:45



US3402194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:27:28

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:40:49
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 20:38:35

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'USA-US059-2020-MRNA-1273-P301000018'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Frank'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Eder'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '1290 Upper Front Street'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Binghamton'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'NY'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '13901'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered 'US'	System	18 Nov 2020 15:54:28



**US3402194**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:28**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Dec 2020 13:35:40
User entered '4'	System	02 Dec 2020 17:42:00
User entered '3'	System	24 Nov 2020 15:25:57
User entered '2'	System	20 Nov 2020 15:03:14
User entered '1'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'USA-US059-2020-MRNA-1273-P301000018'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Frank'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Eder'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '1290 Upper Front Street'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Binghamton'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'NY'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '13901'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered 'US'	System	18 Nov 2020 15:54:28



**US3402194**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:28**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Dec 2020 13:35:40
User entered '4'	System	02 Dec 2020 17:42:00
User entered '3'	System	24 Nov 2020 15:25:57
User entered '2'	System	20 Nov 2020 15:03:14
User entered '1'	System	18 Nov 2020 15:54:28

**US3402194**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000018**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:27:28**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
User entered '18/Nov/2020 15:54'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:27:28

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'USA-US059-2020-MRNA-1273-P301000018'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Frank'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Eder'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '1290 Upper Front Street'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Binghamton'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'NY'	System	18 Nov 2020 15:53:59



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '13901'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered 'US'	System	18 Nov 2020 15:54:28

**US3402194**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:28**

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '5'	System	08 Dec 2020 13:35:40
User entered '4'	System	02 Dec 2020 17:42:00
User entered '3'	System	24 Nov 2020 15:25:57
User entered '2'	System	20 Nov 2020 15:03:14
User entered '1'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:27:28

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
User entered '20/Nov/2020 15:03'	System	20 Nov 2020 15:03:14

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:27:28

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:25:41
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 15:03:14

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'USA-US059-2020-MRNA-1273-P301000018'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Frank'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Eder'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '1290 Upper Front Street'	System	18 Nov 2020 15:53:59



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Binghamton'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'NY'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '13901'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered 'US'	System	18 Nov 2020 15:54:28

**US3402194**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:28**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Dec 2020 13:35:40
User entered '4'	System	02 Dec 2020 17:42:00
User entered '3'	System	24 Nov 2020 15:25:57
User entered '2'	System	20 Nov 2020 15:03:14
User entered '1'	System	18 Nov 2020 15:54:28

**US3402194**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000018**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:27:28**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
User entered '24/Nov/2020 15:25'	System	24 Nov 2020 15:25:57

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:27:28

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:41:44
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:29:00
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 15:25:57

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'USA-US059-2020-MRNA-1273-P301000018'	System	18 Nov 2020 15:53:59



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Frank'	System	18 Nov 2020 15:53:59



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Eder'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '1290 Upper Front Street'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Binghamton'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'NY'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '13901'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered 'US'	System	18 Nov 2020 15:54:28

**US3402194**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:28**

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '5'	System	08 Dec 2020 13:35:40
User entered '4'	System	02 Dec 2020 17:42:00
User entered '3'	System	24 Nov 2020 15:25:57
User entered '2'	System	20 Nov 2020 15:03:14
User entered '1'	System	18 Nov 2020 15:54:28

**US3402194**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000018**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:27:28**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:00:28
User entered '02/Dec/2020 12:41'	System	02 Dec 2020 17:42:00



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:27:28

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:00:29
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 13:35:32
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 17:42:00

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'USA-US059-2020-MRNA-1273-P301000018'	System	18 Nov 2020 15:53:59

**US3402194**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:28**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Yes (Y)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59



US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'No (N)'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Frank'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Eder'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '1290 Upper Front Street'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'Binghamton'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered 'NY'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:54:22
User entered '13901'	System	18 Nov 2020 15:53:59

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:29:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:03:03
User entered 'US'	System	18 Nov 2020 15:54:28



**US3402194**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:28**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Dec 2020 13:35:40
User entered '4'	System	02 Dec 2020 17:42:00
User entered '3'	System	24 Nov 2020 15:25:57
User entered '2'	System	20 Nov 2020 15:03:14
User entered '1'	System	18 Nov 2020 15:54:28

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:27:28

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:00:19
User entered '08/Dec/2020 08:35'	System	08 Dec 2020 13:35:40

US3402194

Folder: SAE USA-US059-2020-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:27:28

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:00:22
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 13:35:40