

US3482094 (Prod: Hope Clinic of The Emory Vaccine Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:46:24

All time stamps listed in this document are displayed in GMT

US3482094

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

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[Participant ID](#)

US3482094

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

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US3482094

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3482094

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Date of Birth (MMM yyyy)	(b) (6) 1972
Age	48
Age Units	YEARS
Age (Derived)	48
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) 13 Feb 2021 15:19:45

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 15:19:45

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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) 13 Feb 2021 15:19:45

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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) 13 Feb 2021 15:19:45

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Condition	CATARACT SURGERY
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Condition	HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 15:19:45

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Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:19:45

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	20 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	9:00 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 9:00
Height ( <i>xxx.x</i> )	173 cm
Weight ( <i>xxx.x</i> )	70.7 kg
BMI ( <i>xxx.x</i> )	23.62257 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:19:45

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:19:45

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

MUSICIAN PLAYING AT  
DIFFERENT VENUES

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:19:45

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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>	True
<b>Specify</b>	RESIDENT LIVING IN A COMMUNITY WITH PERSON TO PERSON TRANSMISSION.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 15:19:45

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What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 105894

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

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) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	9:00 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 9:00
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	10:42 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:42
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

20 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) 13 Feb 2021 15:19:45

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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) 20 AUG 2020

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

Treatment Date and Time (derived) 20 AUG 2020 10:10

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) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	09:40 (24 HR)
Collection date and time (derived)	20 AUG 2020 09:40

US3482094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	9:42	20 AUG 2020 9:42
Nasopharyngeal Swab 2	No		

US3482094

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

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 17:46:24

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 10:45

PC Open Date & Time

20 AUG 2020 10:30

PC Close Date & Time

20 AUG 2020 13:00

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**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 95.4 °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	20 AUG 2020 20:12
PC Open Date & Time	20 AUG 2020 13:55
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

21 AUG 2020 17:08

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 14:56

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

23 AUG 2020 17:25

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 12:53

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

25 AUG 2020 18:55

---

PC Open Date & Time

25 AUG 2020 12:00

---

PC Close Date & Time

26 AUG 2020 11:59

---

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 17:53

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**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 ☐

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

20 AUG 2020 10:30

PC Close Date & Time

20 AUG 2020 13:00

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**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

20 AUG 2020 18:34

PC Open Date & Time

20 AUG 2020 13:55

PC Close Date & Time

21 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 16:22

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59



US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 14:55

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 17:26

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 12:52

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 18:56

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 17:52

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**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 ☐

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

20 AUG 2020 10:30

PC Close Date & Time

20 AUG 2020 13:00

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**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 ☐



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 20:13
PC Open Date & Time	20 AUG 2020 13:55
PC Close Date & Time	21 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**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 ☒

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 16:23
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 14:56
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 3780

EAB) (1725)

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 17:26
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 12:53
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 3780

EAB) (1725)

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 18:58
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

55 of 3780

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 17:53
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 27 AUG 2020 16:34

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3482094

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:46:24

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 AUG 2020 16:34
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3482094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3482094

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482094

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482094

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

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)	22 SEP 2020
Time of assessment (00:00-23:59)	09:13 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 09:13
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

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)	22 SEP 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 10:35
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG



US3482094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3482094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 10:03 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 10:03

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

US3482094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

09:30 (24 HR)

Collection date and time (derived)

22 SEP 2020 09:30

US3482094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	22 SEP 2020 09:35
Nasopharyngeal Swab 2	No		

US3482094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 10:37

PC Open Date & Time

22 SEP 2020 10:23

PC Close Date & Time

22 SEP 2020 12:53

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	23 SEP 2020 09:48
PC Open Date & Time	22 SEP 2020 13:48
PC Close Date & Time	23 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

23 SEP 2020 12:09

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59



US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

24 SEP 2020 14:48

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 16:26

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

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**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 17:50

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 18:16

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

29 SEP 2020 02:20

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**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

22 SEP 2020 10:38

PC Open Date & Time

22 SEP 2020 10:23

PC Close Date & Time

22 SEP 2020 12:53

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**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

23 SEP 2020 09:49

PC Open Date & Time

22 SEP 2020 13:48

PC Close Date & Time

23 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 12:09

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59



US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 14:49

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 16:26

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 17:50

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 18:17

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 02:20

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**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 ☐

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 10:38
PC Open Date & Time	22 SEP 2020 10:23
PC Close Date & Time	22 SEP 2020 12:53

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**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 ☐



US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 09:49
PC Open Date & Time	22 SEP 2020 13:48
PC Close Date & Time	23 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:10
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 14:49
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 16:27
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

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 ☒

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EAB) (1725)



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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 17:51
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 18:17
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**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 ☒

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 02:20
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 30 SEP 2020 00:38

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3482094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:46:24

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 00:38
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3482094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3482094

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482094

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482094

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:19:45

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:19:46

Generated On: 09 Jun 2021 17:46:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:19:46

Generated On: 09 Jun 2021 17:46:24

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) \_\_\_\_\_

US3482094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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.*



US3482094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:19:46

Generated On: 09 Jun 2021 17:46:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

10:18 (24 HR)

Collection date and time (derived)

22 OCT 2020 10:18

US3482094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:19:46

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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

27 OCT 2020 01:46:45

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	05 NOV 2020 08:06:01
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 10:27:17
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 10:36:01
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59



US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 06:48:11

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 10:34:42

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 DEC 2020 13:03:16
Patient Cloud Open Date & Time	12 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
126 of 3780	

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 05:21:56

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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

26 DEC 2020 09:56:32

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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

02 JAN 2021 23:10:22

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 JAN 2021 15:58:35
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59



US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 09:53:36

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 00:02:42

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 08:55:15

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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

06 FEB 2021 00:33:42

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 00:50:29

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 19:02:33

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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	27 FEB 2021 09:54:20
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 18:51:57
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59



US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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

14 MAR 2021 23:31:59

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 23:47:46

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 17:45:09

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

Date and time of submission

03 APR 2021 13:53:45

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 10:33:52

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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

18 APR 2021 23:29:40

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	24 APR 2021 08:56:32
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JUN 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JUN 2021 23:59
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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 AUG 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2021 23:59
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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

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 ☐



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 NOV 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JAN 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 APR 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUL 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

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 ☐



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUL 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**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 ☐



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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



**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3482094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3482094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3482094

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:46:24

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		27 FEB 2021 09:54:08

US3482094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3482094

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3482094

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3482094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3482094

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3482094

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

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

Visit date (dd MMM yyyy)	11 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

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) \_\_\_\_\_

US3482094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

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.*

US3482094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	11:25 (24 HR)
Collection date and time (derived)	11 MAR 2021 11:25



US3482094

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482094

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Was Contact Attempted? Yes ☒ No ☐

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

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

Comments 4/20/21: LEFT VOICEMAIL AND SENT EMAIL

If Contact Not Made, please provide Comments

US3482094

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3482094**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

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*

**US3482094**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

Date of Contact	13 OCT 2020
Time of Contact	08:40
Date and Time of Contact (derived)	13 OCT 2020 08:40
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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"/>

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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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US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input 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 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 (4)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Form: Symptom Log (5)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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"/>

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input 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 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

Date of Visit 13 OCT 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 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

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

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

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[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

---

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Folder: Covid-19 Assessment 17 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

Date of Contact	17 DEC 2020
Time of Contact	10:31
Date and Time of Contact (derived)	17 DEC 2020 10:31
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	99 F
-------------	------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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"/>

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input 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 17 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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"/>

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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Form: Symptom Log (3)

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



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Form: Symptom Log (3)

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

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Form: Symptom Log (4)

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Symptom Day

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

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

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Form: Symptom Log (4)

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

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Form: Symptom Log (4)

Data signed: (b) (4) 17 Apr 2021 03:09:48

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

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Form: Symptom Log (5)

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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 (5)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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



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Form: Symptom Log (5)

Data signed: (b) (4) 17 Apr 2021 03:09:48

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

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Form: Symptom Log (6)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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

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Form: Symptom Log (6)

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Generated On: 09 Jun 2021 17:46:24

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

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Form: Symptom Log (7)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Form: Symptom Log (7)

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

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



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Form: Symptom Log (7)

Data signed: (b) (4) 17 Apr 2021 03:09:48

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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 17 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.5 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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 17 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020
------	-------------

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

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

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

Temperature	98.2 F
-------------	--------

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

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

Shortness of Breath	None <input 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 17 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	101 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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 17 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	101.5 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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Form: Symptom Log (12)

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Generated On: 09 Jun 2021 17:46:24

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

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Form: Symptom Log (12)

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

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Form: Symptom Log (13)

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input 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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Form: Symptom Log (13)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.7 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 type="radio"/>
	Moderate	<input checked="" 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 (13)

Data signed: (b) (4) 17 Apr 2021 03:09:48

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



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Form: Symptom Log (13)

Data signed: (b) (4) 17 Apr 2021 03:09:48

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

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Form: Symptom Log (14)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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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Form: Symptom Log (14)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	103.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" 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 type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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EAB) (1725)		

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Form: Symptom Log (14)

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

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Form: Symptom Log (14)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Form: Symptom Log (15)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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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Form: Symptom Log (15)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	103.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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EAB) (1725)		

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Form: Symptom Log (15)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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



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Form: Symptom Log (15)

Data signed: (b) (4) 17 Apr 2021 03:09:48

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

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Form: Symptom Log (16)

Data signed: (b) (4) 17 Apr 2021 03:09:48

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Symptom Day

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

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Form: Symptom Log (16)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	103.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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EAB) (1725)		

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Form: Symptom Log (16)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Form: Symptom Log (16)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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 17 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

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

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

Cough	None <input 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 type="radio"/>
	Moderate <input checked="" 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 17 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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 17 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 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 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 17 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	102.0 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"/>

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 (21)

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

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Form: Symptom Log (22)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (22)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 (22)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Form: Symptom Log (23)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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 checked="" 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 (23)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	100.0 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"/>

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



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Form: Symptom Log (23)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Form: Symptom Log (24)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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 checked="" 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 (25)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (25)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (25)

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

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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"/>

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 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 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		454 of 3780
EAB) (1725)		

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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 checked="" 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 17 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 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 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		458 of 3780
EAB) (1725)		

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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 checked="" 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 17 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

Date	05 JAN 2021
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 17 Apr 2021 03:09:48

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

Date of Visit 17 DEC 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 17 DEC 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

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

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 25 DEC 2020

End Date 27 DEC 2020

Oxygen Saturation 93 %

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 \_\_\_\_\_

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

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

**Ventilator Support:**

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

Date of Contact	17 NOV 2020
Time of Contact	17:00
Date and Time of Contact (derived)	17 NOV 2020 17:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		471 of 3780
EAB) (1725)		

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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 (3)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

	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	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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EAB) (1725)

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Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

	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	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

	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	98 %
---------------	------

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 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 17 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

	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	98 %	
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 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 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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"/>

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

	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	99 %
---------------	------

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

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

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

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

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

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

	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	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:04:37

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

Date of Visit	18 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	18 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 NOV 2020
Day 5	Yes	22 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit (3)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	19 DEC 2020
Day 5	Yes	21 DEC 2020
Day 7	Yes	23 DEC 2020
Day 9	Yes	26 DEC 2020
Day 14	Yes	30 DEC 2020
Day 21	Yes	06 JAN 2021
Day 28	Yes	14 JAN 2021

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

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

Visit date (dd MMM yyyy)	13 OCT 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 08:40
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3482094

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 OCT 2020

US3482094

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

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

Visit date (dd MMM yyyy)	18 NOV 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
------------	--------

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 NOV 2020
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 15:19
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3482094

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 NOV 2020

US3482094

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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	SICKD1

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 DEC 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	17 DEC 2020 10:36
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 DEC 2020

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

US3482094

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

17 DEC 2020

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:04:35

Generated On: 09 Jun 2021 17:46:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 JAN 2021
Time of assessment ( <i>00:00-23:59</i> )	9:50 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 9:50
Temperature ( <i>xxx.x</i> )	98.5 F
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> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

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.*

US3482094

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 JAN 2021

US3482094

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3482094

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:11:44

Generated On: 09 Jun 2021 17:46:24

Date of updated informed consent ( <i>dd MMM yyyy</i> )	21 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> )	21 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	



US3482094

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

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

Collection date (dd MMM yyyy)	21 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	11:31 (24 HR)
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Collection date and time (derived)	21 JAN 2021 11:31
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US3482094

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 23:04:38

Generated On: 09 Jun 2021 17:46:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	11:26
Collection Date and Time (derived)	21 JAN 2021 11:26

US3482094

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 03:15:05

Generated On: 09 Jun 2021 17:46:24

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3482094

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

AEID

Adverse event

UPPER RESPIRATORY  
INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3482094

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	COUGH, RUNNY NOSE, NASAL CONGESTION, SORE THROAT SYMPTOMS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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US3482094

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

AEID

Adverse event

JOINT ACHES, GENERALIZED

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

AEID

Adverse event

MYALGIAS, GENERALIZED

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

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

US3482094

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

AEID	USA-US106-2020-MRNA-1273-P30 1000011
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	09 DEC 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)	5 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 03:15:00

Generated On: 09 Jun 2021 17:46:24

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SYMPTOMATIC COVID-19, MEETING SEVERE CLASSIFICATION BECAUSE PULSE OX WENT TO 93%. WAS TREATED WITH A NUMBER OF MEDS, AS REPORTED, AND ULTIMATELY RESOLVED.

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Data signed:** (b) (4) 13 Mar 2021 03:15:00

**Generated On: 09 Jun 2021 17:46:24**

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

---

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

Yes ☒

No ☐

---

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

---

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication RYMED

Prophylaxis Yes ☐  
No ☒

Indication UPPER RESPIRATORY (URI)  
SYMPTOMS

Dose per administration 2/10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 03:23:10

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Name of Medication CENTRUM MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH PROMOTION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 03:23:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 03:23:10

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Name of Medication AIRBORNE SUPPLEMENT  
(VITAMINS C & E, ECHINACEA  
& GINGER)

Prophylaxis Yes ☒  
No ☐

Indication HEALTH PROMOTION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 03:23:10

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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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 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 (4)

Data signed: (b) (4) 23 Apr 2021 03:23:10

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication BODY ACHES (COVID-19)

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 (4)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 17 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 12

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) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 17 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
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 (6)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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)		18 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
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 (7)

Data signed: (b) (4) 23 Apr 2021 03:23:10

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Name of Medication CETIRIZINE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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)		18 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 JAN 2021
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 (8)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 162

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 03:23:10

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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)	17 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 FEB 2021	
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 (9)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 8

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 (9)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
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) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
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 (11)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
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 (12)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication FEVER RELATED TO COVID19

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 (12)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication DEXMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication COVID19

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 ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication ALBUTEROL NEBULIZER

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

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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EAB) (1725)

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	05 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT FOR POSSIBLE  
SECONDARY INFECTION DUE  
TO CONTINUED HIGH FEVER

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT FOR POSSIBLE  
SECONDARY INFECTION DUE  
TO CONTINUED HIGH FEVER

Dose per administration 250

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 (16)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 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 (17)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT FOR POSSIBLE  
SECONDARY INFECTION DUE  
TO CONTINUED HIGH FEVER

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
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) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 2

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)

Data signed: (b) (4) 23 Apr 2021 03:23:10

Generated On: 09 Jun 2021 17:46:24

	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)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 DEC 2020	CHEST XRAY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:46:24

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



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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:46:24

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 ☐

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

SAEID	USA-US106-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

SAEID	USA-US106-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/DEC/2020 09:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

SAEID	USA-US106-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/JAN/2021 13:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

SAEID	USA-US106-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/JAN/2021 12:28
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.	True

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

SAEID	USA-US106-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	25/JAN/2021 10:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

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Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

SAEID	USA-US106-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/JAN/2021 11:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

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Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Mar 2021 22:23:16

Generated On: 09 Jun 2021 17:46:24

SAEID	USA-US106-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/MAR/2021 13:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3482094 (Prod: Hope Clinic of The Emory Vaccine Center)

**US3482094**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:46:24**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:44:18
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'US3482094'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 12:59:47

**US3482094**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:47:08
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:31:57

US3482094

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 12:59:48

US3482094

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:47:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Clinic (Clinic)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:31:57

**US3482094**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'SCRN'	System	20 Aug 2020 14:31:57

**US3482094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:19
User entered (b) (6) 1972'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 12:59:49

US3482094

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:46:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:20
User entered '48'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26



**US3482094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:46:24**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'YEARS'	System	20 Aug 2020 14:32:26

**US3482094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:46:24**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered '48'	System	20 Aug 2020 14:33:50

US3482094

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:46:24

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 16:35:25
User entered 'Male (M)'	Geoffrey Kamau (b) (4)	20 Aug 2020 14:32:26

US3482094

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:46:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26

US3482094

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:46:24

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:32
User entered 'l'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26

US3482094

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:46:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:35
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26

**US3482094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:46:24**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:35
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26

**US3482094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:46:24**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:35
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26



US3482094

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:46:24

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:35
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26

**US3482094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:46:24**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:35
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26

US3482094

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:46:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:35
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26

**US3482094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:46:24**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:35
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26

**US3482094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:46:24**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:35:35
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:32:26

US3482094

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:46:24

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:06
User entered '20 Aug 2020'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:33:50

**US3482094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:46:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'Aug 2020'	System	20 Aug 2020 14:33:50

**US3482094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:46:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered '2020'	System	20 Aug 2020 14:33:50



US3482094

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:46:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:06
User entered 'Amendment 3 (3)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:33:50

US3482094

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:46:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:06
User entered 'Yes (Y)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:33:50

US3482094

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:46:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:06
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:33:50

**US3482094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:46:24**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:06
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:33:50

US3482094

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:46:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:06
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:33:50

US3482094

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:46:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 12:59:48

**US3482094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:46:24**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'I'	System	20 Aug 2020 14:33:57

**US3482094**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:46:24**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:36:41
User entered 'Yes (Y)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:33:57



US3482094

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:46:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:44:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:20:33

US3482094

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:46:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Aug 2020 17:22:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:22:29
Data point term sent to Coder	System	20 Aug 2020 17:21:50
User entered 'Cataract surgery'	Geoffrey Kamau (b) (4)	20 Aug 2020 17:21:27
	(b) (4)	

**US3482094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:46:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:07
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'un UNK 1984'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:21:27

**US3482094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '0'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:21:27

**US3482094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:21:27

**US3482094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:46:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:15
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'un UNK 1984'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:21:27

**US3482094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:16
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '0'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:21:27

**US3482094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'Jan 1984'	System	20 Aug 2020 17:21:27



**US3482094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered '1984'	System	20 Aug 2020 17:21:27

**US3482094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'Jan 1984'	System	20 Aug 2020 17:21:27

**US3482094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered '1984'	System	20 Aug 2020 17:21:27

US3482094

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:46:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:24
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Hernia repair, LLT: Hernia repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Aug 2020 17:24:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:24:28
Data point term sent to Coder	System	20 Aug 2020 17:22:53
User entered 'Hernia repair'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:22:19

**US3482094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:46:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:26
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'un UNK 2004'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:22:19

**US3482094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '0'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:22:19

**US3482094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:22:19

**US3482094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:46:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:35
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'un UNK 2004'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:22:19



**US3482094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:38
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '0'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:22:19

**US3482094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'Jan 2004'	System	20 Aug 2020 17:22:19

**US3482094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered '2004'	System	20 Aug 2020 17:22:19

**US3482094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'Jan 2004'	System	20 Aug 2020 17:22:19

**US3482094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered '2004'	System	20 Aug 2020 17:22:19

US3482094

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:46:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:53
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:24:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:24:30
Data point term sent to Coder	System	20 Aug 2020 17:23:57
User entered 'Appendectomy'	Geoffrey Kamau (b) (4)	20 Aug 2020 17:23:18

**US3482094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:46:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'un UNK 2014'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:23:18

**US3482094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '0'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:23:18



**US3482094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:01
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:23:18

**US3482094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:46:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'un UNK 2014'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:23:18

**US3482094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '0'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:23:18

**US3482094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'Jan 2014'	System	20 Aug 2020 17:23:18

**US3482094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered '2014'	System	20 Aug 2020 17:23:18

**US3482094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'Jan 2014'	System	20 Aug 2020 17:23:18

**US3482094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered '2014'	System	20 Aug 2020 17:23:18

US3482094

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:46:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:24:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:24:30
Data point term sent to Coder	System	20 Aug 2020 17:24:00
User entered 'Acid reflux'	Geoffrey Kamau (b) (4)	20 Aug 2020 17:23:59



**US3482094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:46:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:17
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'un UNK 1995'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:23:59

**US3482094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:18
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '0'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:23:59

**US3482094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:23:59

**US3482094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:46:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:23:59

**US3482094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:24
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '0'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:23:59

**US3482094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'Jan 1995'	System	20 Aug 2020 17:23:59

**US3482094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered '1995'	System	20 Aug 2020 17:23:59

**US3482094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered empty.	System	20 Aug 2020 17:23:59



**US3482094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered empty.	System	20 Aug 2020 17:23:59

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:47:48
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	08 Sep 2020 17:04:22
User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	08 Sep 2020 17:04:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:04:22
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	25 Aug 2020 19:12:58
User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	20 Aug 2020 17:24:58
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:24:58

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:47:51
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:04:22
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:24:58

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:47:58
User entered '9:00' reason for change: Data Entry Error	Geoffrey Kamau (b) (4)	25 Aug 2020 19:12:58
User entered empty.	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 17:24:58
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered '20 Aug 2020 9:00'	System	08 Sep 2020 17:04:22
User entered empty.	System	20 Aug 2020 17:24:58

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:10
User entered '173' cm	Geoffrey Kamau (b) (4)	20 Aug 2020 17:24:58
DataPoint set to visible.	(b) (4) System	20 Aug 2020 14:33:57

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:13
User entered '70.7' kg	Geoffrey Kamau (b) (4)	20 Aug 2020 17:24:58
DataPoint set to visible.	(b) (4) System	20 Aug 2020 14:33:57

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
Amendment Manager: User entered '23.62257'	System	17 Sep 2020 00:15:30
User entered '23.6'	System	20 Aug 2020 17:24:58
DataPoint set to visible.	System	20 Aug 2020 14:33:57



**US3482094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'kg/m2'	System	20 Aug 2020 17:24:58
DataPoint set to visible.	System	20 Aug 2020 14:33:57

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:04:22
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:24:58

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:20
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:24:58

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:33
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:24:58

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:04:22
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:24:58

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'bpm'	System	08 Sep 2020 17:04:22
User entered empty.	System	20 Aug 2020 17:24:58

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:04:22
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:24:58

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'breaths/min'	System	08 Sep 2020 17:04:22
User entered empty.	System	20 Aug 2020 17:24:58



US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:04:22
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:24:58

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'mmHg'	System	08 Sep 2020 17:04:22
User entered empty.	System	20 Aug 2020 17:24:58

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:49:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:04:22
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:24:58

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User entered 'mmHg'	System	08 Sep 2020 17:04:22
User entered empty.	System	20 Aug 2020 17:24:58

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37

US3482094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37

US3482094

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:46
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:25:45

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:46:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '20 Aug 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:25:45



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:14
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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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)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:16
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:18
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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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)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:20
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:23
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:24
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:26
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:27
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:29
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:30
User entered 'No (N)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

US3482094

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:34
User entered 'Yes (Y)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:39
User entered 'Yes (Y)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:40
User entered 'Musician playing at different venues'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '0'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:58
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:58
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13



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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:58
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:58
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:40:07
User entered '0'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'I'	Geoffrey Kamau (b) (4)	20 Aug 2020 14:36:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:46:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:08:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:58:55
User entered 'Resident living in a community with person to person transmission.'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:36:13

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 17:26:25

US3482094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '20 Aug 2020'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 17:26:25

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Clinic (Clinic)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 17:26:25



**US3482094**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'VISIT1'	System	20 Aug 2020 17:26:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:46:24

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:50:08

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:46:24

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:47:08
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:47:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 13:50:08
User entered '105894' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:50:08

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:46:24

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:50:08

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:46:24**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:37:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:46:24

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:37:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:46:24

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:37:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:46:24

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:37:42



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:46:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:37:42

US3482094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:46:24

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 04:07:17
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 19:41:10
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 19:41:01
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 22:24:48
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 01:40:46
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:40:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:46:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:20:57
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated to ND' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:22:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:22:39
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:14:40
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:46:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:22:39
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:46:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:20:57
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated to ND' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:22:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:22:39
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:14:40
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:46:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:22:39
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User accepted default value 'Pre-Dose (PREDOSE)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered 'Yes (Y)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00



US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '20 Aug 2020'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '9:00'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered '20 Aug 2020 9:00'	System	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '98.0' F	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered 'Oral (Oral)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '60'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'bpm'	System	20 Aug 2020 17:34:00



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '16'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'breaths/min'	System	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '117'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'mmHg'	System	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '70'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'mmHg'	System	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:46:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Roupheel (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:20:57
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated to ND' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:22:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:22:39
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:14:40
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:46:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:22:39
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User accepted default value 'Post-Dose (POSTDOSE)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered 'Yes (Y)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '20 Aug 2020'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:47:05
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 17:34:00
User entered '10:42'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

US3482094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered '20 Aug 2020 10:42'	System	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '97.9' F	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered 'Oral (Oral)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '62'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'bpm'	System	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '16'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'breaths/min'	System	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '113'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'mmHg'	System	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:50:33
User entered '77'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 17:34:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'mmHg'	System	20 Aug 2020 17:34:00



US3482094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 17:34:39

US3482094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '20 Aug 2020'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 17:34:39

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:04:55
User entered 'Yes (Y)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:38:37

US3482094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:04:55
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:38:37

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:04:55
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:38:37

US3482094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 14:38:37

US3482094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:04:55
User entered '20 Aug 2020'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:38:37

US3482094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:04:55
User entered '10:10'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:38:37



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered '20 Aug 2020 10:10'	System	20 Aug 2020 14:38:37

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:04:55
User entered 'Right Arm (RIGHT ARM)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:38:37

US3482094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:04:55
User entered 'ONCE'	System	20 Aug 2020 14:38:37

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 14:38:37

US3482094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:41:30

US3482094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '20 Aug 2020'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:41:30

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:46:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '09:40'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:41:30

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered '20 Aug 2020 09:40'	System	20 Aug 2020 14:41:30



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:46:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '20 Aug 2020'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:42:11

US3482094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:46:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:42:11

US3482094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:46:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:42:11

US3482094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:46:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '9:42'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:42:11

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered '20 Aug 2020 9:42'	System	20 Aug 2020 14:42:11

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Geoffrey Kamau (b) (4) (b) (4)	20 Aug 2020 14:42:11

US3482094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:46:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:42:11

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:46:24**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 14:42:11



**US3482094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered empty.	System	20 Aug 2020 14:42:11

US3482094

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4)	20 Aug 2020 17:34:53

**US3482094**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'I'	System	20 Aug 2020 17:34:53

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T10:44:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e2f4586e-4fe8-4458-900c-16558b8405f9'	System	20 Aug 2020 14:45:07
User entered 'Yes (Y)'	System	20 Aug 2020 14:45:07

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T10:44:52', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e2f4586e-4fe8-4458-900c-16558b8405f9'	System	20 Aug 2020 14:45:07
User entered '97.9'	System	20 Aug 2020 14:45:07

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T10:44:57', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e2f4586e-4fe8-4458-900c-16558b8405f9'	System	20 Aug 2020 14:45:07
User entered 'No (N)'	System	20 Aug 2020 14:45:07

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T10:45:03', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e2f4586e-4fe8-4458-900c-16558b8405f9'	System	20 Aug 2020 14:45:07
User entered '20 Aug 2020 10:45'	System	20 Aug 2020 14:45:07



US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '20 Aug 2020 10:30'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '20 Aug 2020 13:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:12:18', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '814e85aa-f922-4414-b995-d451295b0d47'	System	21 Aug 2020 00:12:37
User entered 'Yes (Y)'	System	21 Aug 2020 00:12:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:12:26', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '814e85aa-f922-4414-b995-d451295b0d47'	System	21 Aug 2020 00:12:37
User entered '95.4'	System	21 Aug 2020 00:12:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:12:29', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '814e85aa-f922-4414-b995-d451295b0d47'	System	21 Aug 2020 00:12:37
User entered 'No (N)'	System	21 Aug 2020 00:12:37

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:12:33', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '814e85aa-f922-4414-b995-d451295b0d47'	System	21 Aug 2020 00:12:37
User entered '20 Aug 2020 20:12'	System	21 Aug 2020 00:12:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '20 Aug 2020 13:55'	System	20 Aug 2020 14:38:37



US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 2'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T17:08:25', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b7f2ffe7-fb22-45a6-9470-180c16120b83'	System	21 Aug 2020 21:08:43
User entered 'Yes (Y)'	System	21 Aug 2020 21:08:43

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T17:08:32', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b7f2ffe7-fb22-45a6-9470-180c16120b83'	System	21 Aug 2020 21:08:43
User entered '97.7'	System	21 Aug 2020 21:08:43

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T17:08:35', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b7f2ffe7-fb22-45a6-9470-180c16120b83'	System	21 Aug 2020 21:08:43
User entered 'No (N)'	System	21 Aug 2020 21:08:43

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T17:08:40', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b7f2ffe7-fb22-45a6-9470-180c16120b83'	System	21 Aug 2020 21:08:43
User entered '21 Aug 2020 17:08'	System	21 Aug 2020 21:08:43

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 14:38:37



US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 3'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '4a27e833-8ca3-4ce4-9977-0854be7d460e'	System	22 Aug 2020 18:56:16
User entered 'Yes (Y)'	System	22 Aug 2020 18:56:16

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:06', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '4a27e833-8ca3-4ce4-9977-0854be7d460e'	System	22 Aug 2020 18:56:16
User entered '99.0'	System	22 Aug 2020 18:56:16

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:09', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '4a27e833-8ca3-4ce4-9977-0854be7d460e'	System	22 Aug 2020 18:56:16
User entered 'No (N)'	System	22 Aug 2020 18:56:16

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:13', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '4a27e833-8ca3-4ce4-9977-0854be7d460e'	System	22 Aug 2020 18:56:16
User entered '22 Aug 2020 14:56'	System	22 Aug 2020 18:56:16

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 4'	System	20 Aug 2020 14:38:37



US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:25:36', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '86cca832-7509-4794-8eca-96dbca66bea1'	System	23 Aug 2020 21:25:52
User entered 'Yes (Y)'	System	23 Aug 2020 21:25:52

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:25:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '86cca832-7509-4794-8eca-96dbca66bea1'	System	23 Aug 2020 21:25:52
User entered '97.4'	System	23 Aug 2020 21:25:52

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:25:45', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '86cca832-7509-4794-8eca-96dbca66bea1'	System	23 Aug 2020 21:25:52
User entered 'No (N)'	System	23 Aug 2020 21:25:52

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:25:49', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '86cca832-7509-4794-8eca-96dbca66bea1'	System	23 Aug 2020 21:25:52
User entered '23 Aug 2020 17:25'	System	23 Aug 2020 21:25:52

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 5'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:53:18', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '42d93dfa-86b0-4463-9346-b6b4abf47556'	System	24 Aug 2020 16:53:33
User entered 'Yes (Y)'	System	24 Aug 2020 16:53:33



US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:53:23', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '42d93dfa-86b0-4463-9346-b6b4abf47556'	System	24 Aug 2020 16:53:33
User entered '98.0'	System	24 Aug 2020 16:53:33

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:53:26', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '42d93dfa-86b0-4463-9346-b6b4abf47556'	System	24 Aug 2020 16:53:33
User entered 'No (N)'	System	24 Aug 2020 16:53:33

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:53:31', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '42d93dfa-86b0-4463-9346-b6b4abf47556'	System	24 Aug 2020 16:53:33
User entered '24 Aug 2020 12:53'	System	24 Aug 2020 16:53:33

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 6'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:55:10', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '5d9b5722-3a9d-4242-9b8f-3479416a5c22'	System	25 Aug 2020 22:55:33
User entered 'Yes (Y)'	System	25 Aug 2020 22:55:33

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:55:21', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '5d9b5722-3a9d-4242-9b8f-3479416a5c22'	System	25 Aug 2020 22:55:33
User entered '97.9'	System	25 Aug 2020 22:55:33



US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:55:25', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '5d9b5722-3a9d-4242-9b8f-3479416a5c22'	System	25 Aug 2020 22:55:33
User entered 'No (N)'	System	25 Aug 2020 22:55:33

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:55:30', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '5d9b5722-3a9d-4242-9b8f-3479416a5c22'	System	25 Aug 2020 22:55:33
User entered '25 Aug 2020 18:55'	System	25 Aug 2020 22:55:33

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 7'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:52:54', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c87aad6f-01e5-4c22-9626-32c741aed1e1'	System	26 Aug 2020 21:53:06
User entered 'Yes (Y)'	System	26 Aug 2020 21:53:06

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:52:59', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c87aad6f-01e5-4c22-9626-32c741aed1e1'	System	26 Aug 2020 21:53:06
User entered '98.0'	System	26 Aug 2020 21:53:06

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:53:01', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c87aad6f-01e5-4c22-9626-32c741aed1e1'	System	26 Aug 2020 21:53:06
User entered 'No (N)'	System	26 Aug 2020 21:53:06



US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:53:04', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c87aad6f-01e5-4c22-9626-32c741aed1e1'	System	26 Aug 2020 21:53:06
User entered '26 Aug 2020 17:53'	System	26 Aug 2020 21:53:06

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38



US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '20 Aug 2020 10:30'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '20 Aug 2020 13:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T18:34:29', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8ac2b54b-4f3b-48bf-b86d-cfefa86d3e0f'	System	20 Aug 2020 22:34:55
User entered 'None (1)'	System	20 Aug 2020 22:34:55

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T18:34:33', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8ac2b54b-4f3b-48bf-b86d-cfefa86d3e0f'	System	20 Aug 2020 22:34:55
User entered 'No (N)'	System	20 Aug 2020 22:34:55



US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T18:34:36', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8ac2b54b-4f3b-48bf-b86d-cfefa86d3e0f'	System	20 Aug 2020 22:34:55
User entered 'No (N)'	System	20 Aug 2020 22:34:55

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T18:34:46', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8ac2b54b-4f3b-48bf-b86d-cfefa86d3e0f'	System	20 Aug 2020 22:34:55
User entered 'None (1)'	System	20 Aug 2020 22:34:55

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T18:34:52', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8ac2b54b-4f3b-48bf-b86d-cfefa86d3e0f'	System	20 Aug 2020 22:34:55
User entered '20 Aug 2020 18:34'	System	20 Aug 2020 22:34:55

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '20 Aug 2020 13:55'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 2'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:22:21', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7694e765-5f84-4959-86ab-81e19d3b8fed'	System	21 Aug 2020 20:22:54
User entered 'None (1)'	System	21 Aug 2020 20:22:54

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:22:28', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7694e765-5f84-4959-86ab-81e19d3b8fed'	System	21 Aug 2020 20:22:54
User entered 'No (N)'	System	21 Aug 2020 20:22:54



US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:22:32', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7694e765-5f84-4959-86ab-81e19d3b8fed'	System	21 Aug 2020 20:22:54
User entered 'No (N)'	System	21 Aug 2020 20:22:54

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:22:46', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7694e765-5f84-4959-86ab-81e19d3b8fed'	System	21 Aug 2020 20:22:54
User entered 'None (1)'	System	21 Aug 2020 20:22:54

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:22:51', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7694e765-5f84-4959-86ab-81e19d3b8fed'	System	21 Aug 2020 20:22:54
User entered '21 Aug 2020 16:22'	System	21 Aug 2020 20:22:54

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 3'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:55:37', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '31718e96-441d-4a96-a05d-0e7c9c642070'	System	22 Aug 2020 18:55:54
User entered 'None (1)'	System	22 Aug 2020 18:55:54

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:55:39', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '31718e96-441d-4a96-a05d-0e7c9c642070'	System	22 Aug 2020 18:55:54
User entered 'No (N)'	System	22 Aug 2020 18:55:54



US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:55:41', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '31718e96-441d-4a96-a05d-0e7c9c642070'	System	22 Aug 2020 18:55:54
User entered 'No (N)'	System	22 Aug 2020 18:55:54

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:55:49', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '31718e96-441d-4a96-a05d-0e7c9c642070'	System	22 Aug 2020 18:55:54
User entered 'None (1)'	System	22 Aug 2020 18:55:54

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:55:52', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '31718e96-441d-4a96-a05d-0e7c9c642070'	System	22 Aug 2020 18:55:54
User entered '22 Aug 2020 14:55'	System	22 Aug 2020 18:55:54

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 4'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:01', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '357745cc-b4f9-4063-b501-921968ca99b3'	System	23 Aug 2020 21:26:20
User entered 'None (1)'	System	23 Aug 2020 21:26:20

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:04', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '357745cc-b4f9-4063-b501-921968ca99b3'	System	23 Aug 2020 21:26:20
User entered 'No (N)'	System	23 Aug 2020 21:26:20



US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:07', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '357745cc-b4f9-4063-b501-921968ca99b3'	System	23 Aug 2020 21:26:20
User entered 'No (N)'	System	23 Aug 2020 21:26:20

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:16', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '357745cc-b4f9-4063-b501-921968ca99b3'	System	23 Aug 2020 21:26:20
User entered 'None (1)'	System	23 Aug 2020 21:26:20

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:19', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '357745cc-b4f9-4063-b501-921968ca99b3'	System	23 Aug 2020 21:26:20
User entered '23 Aug 2020 17:26'	System	23 Aug 2020 21:26:20

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 5'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:51:46', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '01574e08-de72-4f64-ba22-78369b371006'	System	24 Aug 2020 16:52:31
User entered 'None (1)'	System	24 Aug 2020 16:52:31

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:51:50', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '01574e08-de72-4f64-ba22-78369b371006'	System	24 Aug 2020 16:52:31
User entered 'No (N)'	System	24 Aug 2020 16:52:31



US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:51:52', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '01574e08-de72-4f64-ba22-78369b371006'	System	24 Aug 2020 16:52:31
User entered 'No (N)'	System	24 Aug 2020 16:52:31

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:52:20', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '01574e08-de72-4f64-ba22-78369b371006'	System	24 Aug 2020 16:52:31
User entered 'None (1)'	System	24 Aug 2020 16:52:31

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:52:30', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '01574e08-de72-4f64-ba22-78369b371006'	System	24 Aug 2020 16:52:31
User entered '24 Aug 2020 12:52'	System	24 Aug 2020 16:52:31

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 6'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:55:46', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd9b82390-6eeb-4ead-972a-a4e1ead03626'	System	25 Aug 2020 22:56:28
User entered 'None (1)'	System	25 Aug 2020 22:56:28

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:55:49', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd9b82390-6eeb-4ead-972a-a4e1ead03626'	System	25 Aug 2020 22:56:28
User entered 'No (N)'	System	25 Aug 2020 22:56:28



US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:55:52', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd9b82390-6eeb-4ead-972a-a4e1ead03626'	System	25 Aug 2020 22:56:28
User entered 'No (N)'	System	25 Aug 2020 22:56:28

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:56:09', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd9b82390-6eeb-4ead-972a-a4e1ead03626'	System	25 Aug 2020 22:56:28
User entered 'None (1)'	System	25 Aug 2020 22:56:28

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:56:26', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd9b82390-6eeb-4ead-972a-a4e1ead03626'	System	25 Aug 2020 22:56:28
User entered '25 Aug 2020 18:56'	System	25 Aug 2020 22:56:28

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 7'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:52:44', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '79baa1e9-677c-4528-9aec-6848e58b8b81'	System	26 Aug 2020 21:52:51
User entered 'None (1)'	System	26 Aug 2020 21:52:51

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:52:35', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '79baa1e9-677c-4528-9aec-6848e58b8b81'	System	26 Aug 2020 21:52:51
User entered 'No (N)'	System	26 Aug 2020 21:52:51



US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:52:37', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '79baa1e9-677c-4528-9aec-6848e58b8b81'	System	26 Aug 2020 21:52:51
User entered 'No (N)'	System	26 Aug 2020 21:52:51

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:52:39', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '79baa1e9-677c-4528-9aec-6848e58b8b81'	System	26 Aug 2020 21:52:51
User entered 'None (1)'	System	26 Aug 2020 21:52:51

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:52:48', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '79baa1e9-677c-4528-9aec-6848e58b8b81'	System	26 Aug 2020 21:52:51
User entered '26 Aug 2020 17:52'	System	26 Aug 2020 21:52:51

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '20 Aug 2020 10:30'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '20 Aug 2020 13:00'	System	20 Aug 2020 14:38:37



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:12:46', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '80f08030-9dff-4848-93dc-aecad3b29135'	System	21 Aug 2020 00:13:20
User entered 'No interference with activity (1)'	System	21 Aug 2020 00:13:20

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:12:52', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '80f08030-9dff-4848-93dc-aecad3b29135'	System	21 Aug 2020 00:13:20
User entered 'No interference with activity (1)'	System	21 Aug 2020 00:13:20

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:12:55', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '80f08030-9dff-4848-93dc-aecad3b29135'	System	21 Aug 2020 00:13:20
User entered 'None (0)'	System	21 Aug 2020 00:13:20

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:12:59', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '80f08030-9dff-4848-93dc-aecad3b29135'	System	21 Aug 2020 00:13:20
User entered 'None (0)'	System	21 Aug 2020 00:13:20

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:13:01', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '80f08030-9dff-4848-93dc-aecad3b29135'	System	21 Aug 2020 00:13:20
User entered 'None (0)'	System	21 Aug 2020 00:13:20

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:13:06', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '80f08030-9dff-4848-93dc-aecad3b29135'	System	21 Aug 2020 00:13:20
User entered 'None (0)'	System	21 Aug 2020 00:13:20

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:13:12', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '80f08030-9dff-4848-93dc-aecad3b29135'	System	21 Aug 2020 00:13:20
User entered 'No (N)'	System	21 Aug 2020 00:13:20



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-20T20:13:18', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '80f08030-9dff-4848-93dc-aecad3b29135'	System	21 Aug 2020 00:13:20
User entered '20 Aug 2020 20:13'	System	21 Aug 2020 00:13:20

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '20 Aug 2020 13:55'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 2'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:23:07', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '40ac7726-7f3d-4a5c-a15a-1eccd376534d'	System	21 Aug 2020 20:23:48
User entered 'None (0)'	System	21 Aug 2020 20:23:48

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:23:14', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '40ac7726-7f3d-4a5c-a15a-1eccd376534d'	System	21 Aug 2020 20:23:48
User entered 'No interference with activity (1)'	System	21 Aug 2020 20:23:48

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:23:19', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '40ac7726-7f3d-4a5c-a15a-1eccd376534d'	System	21 Aug 2020 20:23:48
User entered 'None (0)'	System	21 Aug 2020 20:23:48

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:23:22', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '40ac7726-7f3d-4a5c-a15a-1eccd376534d'	System	21 Aug 2020 20:23:48
User entered 'None (0)'	System	21 Aug 2020 20:23:48



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:23:27', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '40ac7726-7f3d-4a5c-a15a-1eccd376534d'	System	21 Aug 2020 20:23:48
User entered 'None (0)'	System	21 Aug 2020 20:23:48

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:23:30', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '40ac7726-7f3d-4a5c-a15a-1eccd376534d'	System	21 Aug 2020 20:23:48
User entered 'None (0)'	System	21 Aug 2020 20:23:48

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:23:40', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '40ac7726-7f3d-4a5c-a15a-1eccd376534d'	System	21 Aug 2020 20:23:48
User entered 'No (N)'	System	21 Aug 2020 20:23:48

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-21T16:23:43', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '40ac7726-7f3d-4a5c-a15a-1eccd376534d'	System	21 Aug 2020 20:23:48
User entered '21 Aug 2020 16:23'	System	21 Aug 2020 20:23:48

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 3'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:28', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b1ae79bc-3cb7-4993-b55d-4bfa59ce984e'	System	22 Aug 2020 18:56:54
User entered 'No interference with activity (1)'	System	22 Aug 2020 18:56:54



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:34', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b1ae79bc-3cb7-4993-b55d-4bfa59ce984e'	System	22 Aug 2020 18:56:54
User entered 'None (0)'	System	22 Aug 2020 18:56:54

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:36', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b1ae79bc-3cb7-4993-b55d-4bfa59ce984e'	System	22 Aug 2020 18:56:54
User entered 'None (0)'	System	22 Aug 2020 18:56:54

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:38', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b1ae79bc-3cb7-4993-b55d-4bfa59ce984e'	System	22 Aug 2020 18:56:54
User entered 'None (0)'	System	22 Aug 2020 18:56:54

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b1ae79bc-3cb7-4993-b55d-4bfa59ce984e'	System	22 Aug 2020 18:56:54
User entered 'None (0)'	System	22 Aug 2020 18:56:54

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:44', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b1ae79bc-3cb7-4993-b55d-4bfa59ce984e'	System	22 Aug 2020 18:56:54
User entered 'None (0)'	System	22 Aug 2020 18:56:54

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:47', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b1ae79bc-3cb7-4993-b55d-4bfa59ce984e'	System	22 Aug 2020 18:56:54
User entered 'No (N)'	System	22 Aug 2020 18:56:54

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-22T14:56:50', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b1ae79bc-3cb7-4993-b55d-4bfa59ce984e'	System	22 Aug 2020 18:56:54
User entered '22 Aug 2020 14:56'	System	22 Aug 2020 18:56:54

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 14:38:37



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 4'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:32', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '194aeaf2-356d-42f0-b3a5-d7a74339ed9f'	System	23 Aug 2020 21:27:00
User entered 'No interference with activity (1)'	System	23 Aug 2020 21:27:00

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:38', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '194aeaf2-356d-42f0-b3a5-d7a74339ed9f'	System	23 Aug 2020 21:27:00
User entered 'No interference with activity (1)'	System	23 Aug 2020 21:27:00

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '194aeaf2-356d-42f0-b3a5-d7a74339ed9f'	System	23 Aug 2020 21:27:00
User entered 'None (0)'	System	23 Aug 2020 21:27:00

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:45', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '194aeaf2-356d-42f0-b3a5-d7a74339ed9f' User entered 'None (0)'	System	23 Aug 2020 21:27:00
	System	23 Aug 2020 21:27:00

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:47', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '194aeaf2-356d-42f0-b3a5-d7a74339ed9f'	System	23 Aug 2020 21:27:00
User entered 'None (0)'	System	23 Aug 2020 21:27:00

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:49', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '194aeaf2-356d-42f0-b3a5-d7a74339ed9f'	System	23 Aug 2020 21:27:00
User entered 'None (0)'	System	23 Aug 2020 21:27:00



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '194aeaf2-356d-42f0-b3a5-d7a74339ed9f'	System	23 Aug 2020 21:27:00
User entered 'No (N)'	System	23 Aug 2020 21:27:00

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-23T17:26:59', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '194aeaf2-356d-42f0-b3a5-d7a74339ed9f'	System	23 Aug 2020 21:27:00
User entered '23 Aug 2020 17:26'	System	23 Aug 2020 21:27:00

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 5'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:52:39', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6d98761b-9904-49c3-a147-c9d91cf23f1c'	System	24 Aug 2020 16:53:07
User entered 'No interference with activity (1)'	System	24 Aug 2020 16:53:07

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:52:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6d98761b-9904-49c3-a147-c9d91cf23f1c'	System	24 Aug 2020 16:53:07
User entered 'None (0)'	System	24 Aug 2020 16:53:07

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:52:46', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6d98761b-9904-49c3-a147-c9d91cf23f1c'	System	24 Aug 2020 16:53:07
User entered 'None (0)'	System	24 Aug 2020 16:53:07



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:52:48', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6d98761b-9904-49c3-a147-c9d91cf23f1c'	System	24 Aug 2020 16:53:07
User entered 'None (0)'	System	24 Aug 2020 16:53:07

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:52:51', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6d98761b-9904-49c3-a147-c9d91cf23f1c'	System	24 Aug 2020 16:53:07
User entered 'None (0)'	System	24 Aug 2020 16:53:07

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:52:53', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6d98761b-9904-49c3-a147-c9d91cf23f1c'	System	24 Aug 2020 16:53:07
User entered 'None (0)'	System	24 Aug 2020 16:53:07

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:52:55', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6d98761b-9904-49c3-a147-c9d91cf23f1c'	System	24 Aug 2020 16:53:07
User entered 'No (N)'	System	24 Aug 2020 16:53:07

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-24T12:53:05', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6d98761b-9904-49c3-a147-c9d91cf23f1c'	System	24 Aug 2020 16:53:07
User entered '24 Aug 2020 12:53'	System	24 Aug 2020 16:53:07

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 6'	System	20 Aug 2020 14:38:37



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:56:37', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a8674e0-d41e-4ec2-8e40-08c32b461ece'	System	25 Aug 2020 22:58:11
User entered 'None (0)'	System	25 Aug 2020 22:58:11

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:57:23', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a8674e0-d41e-4ec2-8e40-08c32b461ece'	System	25 Aug 2020 22:58:11
User entered 'No interference with activity (1)'	System	25 Aug 2020 22:58:11

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:57:29', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a8674e0-d41e-4ec2-8e40-08c32b461ece'	System	25 Aug 2020 22:58:11
User entered 'None (0)'	System	25 Aug 2020 22:58:11

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:57:35', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a8674e0-d41e-4ec2-8e40-08c32b461ece'	System	25 Aug 2020 22:58:11
User entered 'None (0)'	System	25 Aug 2020 22:58:11

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:57:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a8674e0-d41e-4ec2-8e40-08c32b461ece'	System	25 Aug 2020 22:58:11
User entered 'None (0)'	System	25 Aug 2020 22:58:11

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:57:59', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a8674e0-d41e-4ec2-8e40-08c32b461ece'	System	25 Aug 2020 22:58:11
User entered 'None (0)'	System	25 Aug 2020 22:58:11

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:58:06', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a8674e0-d41e-4ec2-8e40-08c32b461ece'	System	25 Aug 2020 22:58:11
User entered 'No (N)'	System	25 Aug 2020 22:58:11

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-25T18:58:08', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a8674e0-d41e-4ec2-8e40-08c32b461ece'	System	25 Aug 2020 22:58:11
User entered '25 Aug 2020 18:58'	System	25 Aug 2020 22:58:11



**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 7'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:53:09', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '47638c87-7f2b-485e-9e17-bcf49af63c44'	System	26 Aug 2020 21:53:41
User entered 'None (0)'	System	26 Aug 2020 21:53:41

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:53:17', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '47638c87-7f2b-485e-9e17-bcf49af63c44'	System	26 Aug 2020 21:53:41
User entered 'No interference with activity (1)'	System	26 Aug 2020 21:53:41

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:53:20', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '47638c87-7f2b-485e-9e17-bcf49af63c44'	System	26 Aug 2020 21:53:41
User entered 'None (0)'	System	26 Aug 2020 21:53:41

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:53:22', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '47638c87-7f2b-485e-9e17-bcf49af63c44'	System	26 Aug 2020 21:53:41
User entered 'None (0)'	System	26 Aug 2020 21:53:41

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:53:24', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '47638c87-7f2b-485e-9e17-bcf49af63c44'	System	26 Aug 2020 21:53:41
User entered 'None (0)'	System	26 Aug 2020 21:53:41



US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:53:26', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '47638c87-7f2b-485e-9e17-bcf49af63c44'	System	26 Aug 2020 21:53:41
User entered 'None (0)'	System	26 Aug 2020 21:53:41

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:53:33', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '47638c87-7f2b-485e-9e17-bcf49af63c44'	System	26 Aug 2020 21:53:41
User entered 'No (N)'	System	26 Aug 2020 21:53:41

US3482094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-26T17:53:36', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '47638c87-7f2b-485e-9e17-bcf49af63c44'	System	26 Aug 2020 21:53:41
User entered '26 Aug 2020 17:53'	System	26 Aug 2020 21:53:41

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 14:38:37

US3482094

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	25 Aug 2020 22:58:11
User entered 'Day 8'	System	25 Aug 2020 22:58:11

US3482094

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:46:24

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-27T16:34:20', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '3f374833-e317-4cf9-aa79-71499d6b77a4'	System	27 Aug 2020 20:34:25
User entered 'None (0)'	System	27 Aug 2020 20:34:25

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-27T16:34:22', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '3f374833-e317-4cf9-aa79-71499d6b77a4'	System	27 Aug 2020 20:34:25
User entered '27 Aug 2020 16:34'	System	27 Aug 2020 20:34:25



**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 22:58:11

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 22:58:11

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	25 Aug 2020 22:58:11
User entered 'Day 8'	System	25 Aug 2020 22:58:11

US3482094

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-27T16:34:28', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '84f63d4b-b641-43ad-8d97-5dd9aa5a67d2'	System	27 Aug 2020 20:34:34
User entered 'No (N)'	System	27 Aug 2020 20:34:34

US3482094

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-08-27T16:34:30', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '84f63d4b-b641-43ad-8d97-5dd9aa5a67d2'	System	27 Aug 2020 20:34:34
User entered '27 Aug 2020 16:34'	System	27 Aug 2020 20:34:34

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 22:58:11

**US3482094**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 22:58:11

**US3482094**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4)	02 Sep 2020 21:43:48



US3482094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:46:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '27 Aug 2020'	(b) (4) Geoffrey Kamau (b) (4)	02 Sep 2020 21:43:48

**US3482094**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Geoffrey Kamau (b) (4)	02 Sep 2020 21:43:48

**US3482094**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4)	02 Sep 2020 21:43:48

US3482094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4)	02 Sep 2020 21:43:54

**US3482094**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'I'	System	02 Sep 2020 21:43:54

**US3482094**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4)	04 Sep 2020 14:49:38

**US3482094**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '3 Sep 2020'	(b) (4) Geoffrey Kamau (b) (4)	04 Sep 2020 14:49:38

US3482094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:46:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Geoffrey Kamau (b) (4)	04 Sep 2020 14:49:38



US3482094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:46:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4)	04 Sep 2020 14:49:38

US3482094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4)	04 Sep 2020 14:49:45

**US3482094**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:16:21
User entered 'I'	System	04 Sep 2020 14:49:45

**US3482094**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:40:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	15 Sep 2020 13:14:05

**US3482094**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:40:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '10 Sep 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	15 Sep 2020 13:14:05

**US3482094**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:40:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	15 Sep 2020 13:14:05

US3482094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:46:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:40:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4)	15 Sep 2020 13:14:05

US3482094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:40:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	15 Sep 2020 13:13:51



**US3482094**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:19
User entered 'I'	System	15 Sep 2020 13:13:51

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:23:49

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '22 Sep 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:23:49

US3482094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Clinic (Clinic)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:23:49

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'VISIT2'	System	22 Sep 2020 14:23:49

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User accepted default value 'Pre-Dose (PREDOSE)'	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:35
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '22 Sep 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52



**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '09:13'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered '22 Sep 2020 09:13'	System	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '98.6' F	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Oral (Oral)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:46:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:44
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '64'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'bpm'	System	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '14'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52



US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'breaths/min'	System	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '103'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'mmHg'	System	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:07:52
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '68'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'mmHg'	System	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User accepted default value 'Post-Dose (POSTDOSE)'	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:20:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:20:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '22 Sep 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52



US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User closed query 'Per CDM: Pre-dose time of assessment is recorded as 09:13 and post-dose time of assessment is recorded as 09:35. Per protocol, 30 minutes is required between assessments. Please review and reconcile, else clarify.' (Site from DM). Query 'Per CDM: Pre-dose time of assessment is recorded as 09:13 and post-dose time of assessment is recorded as 09:35. Per protocol, 30 minutes is required between assessments. Please review and reconcile, else clarify.' answered with 'Corrected' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 06:06:03
User entered '10:35' reason for change: Data Entry Error	Geoffrey Kamau (b) (4) (b) (4)	23 Oct 2020 20:51:40
User opened query 'Per CDM: Pre-dose time of assessment is recorded as 09:13 and post-dose time of assessment is recorded as 09:35. Per protocol, 30 minutes is required between assessments. Please review and reconcile, else clarify.' (Site from DM). User entered '09:35'	Geoffrey Kamau (b) (4) (b) (4), (b) (6)	23 Oct 2020 20:51:29
	(b) (4), (b) (6)	12 Oct 2020 13:28:05
	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered '22 Sep 2020 10:35'	System	23 Oct 2020 20:51:29
User entered '22 Sep 2020 09:35'	System	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:20:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '98.0' F	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:20:33
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Oral (Oral)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:46:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:20:35
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:20:38
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '56'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'bpm'	System	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:20:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '16'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52



US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'breaths/min'	System	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:20:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '120'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'mmHg'	System	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:20:43
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '78'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'mmHg'	System	22 Sep 2020 14:58:52

US3482094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:24:01

US3482094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:22:17
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '22 Sep 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:24:01

US3482094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:08:00
User entered 'Yes (Y)'	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:24:46



US3482094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:08:00
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:24:46

US3482094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:08:00
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:24:46

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:46:24**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 14:24:46

US3482094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:08:00
User entered '22 Sep 2020'	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:24:46

US3482094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:08:00
User entered '10:03'	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:24:46

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:46:24**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered '22 Sep 2020 10:03'	System	22 Sep 2020 14:24:46

US3482094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:08:00
User entered 'Right Arm (RIGHT ARM)'	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:24:46

US3482094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:08:00
User entered 'ONCE'	System	22 Sep 2020 14:24:46



US3482094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:46:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 14:24:46

US3482094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:22:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:26:21

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:22:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '22 Sep 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:26:21

US3482094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:22:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '09:30'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:26:21

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered '22 Sep 2020 09:30'	System	22 Sep 2020 14:26:21

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:16:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '22 Sep 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:27:10

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:27:10

US3482094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:46:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:39:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:27:10



**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:39:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '09:35'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:27:10

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered '22 Sep 2020 09:35'	System	22 Sep 2020 14:27:10

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:27:10

US3482094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:46:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:39:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:27:10

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:46:24**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:39:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:27:10

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered empty.	System	22 Sep 2020 14:27:10

US3482094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:39:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Sep 2020 14:27:19

**US3482094**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'I'	System	22 Sep 2020 14:27:19



US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:37:08', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '169aec3b-4bdf-4d20-8af3-ad3358dc7f1b'	System	22 Sep 2020 14:37:42
User entered 'Yes (Y)'	System	22 Sep 2020 14:37:42

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:37:13', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '169aec3b-4bdf-4d20-8af3-ad3358dc7f1b'	System	22 Sep 2020 14:37:42
User entered '98.0'	System	22 Sep 2020 14:37:42

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:37:18', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '169aec3b-4bdf-4d20-8af3-ad3358dc7f1b'	System	22 Sep 2020 14:37:42
User entered 'No (N)'	System	22 Sep 2020 14:37:42

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:37:40', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '169aec3b-4bdf-4d20-8af3-ad3358dc7f1b'	System	22 Sep 2020 14:37:42
User entered '22 Sep 2020 10:37'	System	22 Sep 2020 14:37:42

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '22 Sep 2020 10:23'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '22 Sep 2020 12:53'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:47:36', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7e1c1110-fd1e-4c03-93e9-214468686ec9'	System	23 Sep 2020 13:48:32
User entered 'Yes (Y)'	System	23 Sep 2020 13:48:32

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:48:23', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7e1c1110-fd1e-4c03-93e9-214468686ec9'	System	23 Sep 2020 13:48:32
User entered '97.5'	System	23 Sep 2020 13:48:32

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:48:27', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7e1c1110-fd1e-4c03-93e9-214468686ec9'	System	23 Sep 2020 13:48:32
User entered 'No (N)'	System	23 Sep 2020 13:48:32

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:48:31', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7e1c1110-fd1e-4c03-93e9-214468686ec9'	System	23 Sep 2020 13:48:32
User entered '23 Sep 2020 09:48'	System	23 Sep 2020 13:48:32

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '22 Sep 2020 13:48'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 2'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:09:30', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'ed251eff-9c1f-458c-b397-9178defa18e2'	System	23 Sep 2020 16:09:47
User entered 'Yes (Y)'	System	23 Sep 2020 16:09:47



US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:09:35', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'ed251eff-9c1f-458c-b397-9178defa18e2'	System	23 Sep 2020 16:09:47
User entered '97.7'	System	23 Sep 2020 16:09:47

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:09:38', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'ed251eff-9c1f-458c-b397-9178defa18e2'	System	23 Sep 2020 16:09:47
User entered 'No (N)'	System	23 Sep 2020 16:09:47

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:09:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'ed251eff-9c1f-458c-b397-9178defa18e2'	System	23 Sep 2020 16:09:47
User entered '23 Sep 2020 12:09'	System	23 Sep 2020 16:09:47

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 3'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:48:27', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b29d3ef3-5d1b-44ee-ad91-25b55cf1d0f3'	System	24 Sep 2020 18:49:01
User entered 'Yes (Y)'	System	24 Sep 2020 18:49:01

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:48:35', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b29d3ef3-5d1b-44ee-ad91-25b55cf1d0f3'	System	24 Sep 2020 18:49:01
User entered '98.1'	System	24 Sep 2020 18:49:01



US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:48:44', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b29d3ef3-5d1b-44ee-ad91-25b55cf1d0f3'	System	24 Sep 2020 18:49:01
User entered 'No (N)'	System	24 Sep 2020 18:49:01

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:48:53', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'b29d3ef3-5d1b-44ee-ad91-25b55cf1d0f3'	System	24 Sep 2020 18:49:01
User entered '24 Sep 2020 14:48'	System	24 Sep 2020 18:49:01

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 4'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:26:23', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '83b41de2-4cb7-45c4-8056-4a8cead9093a'	System	25 Sep 2020 20:26:40
User entered 'Yes (Y)'	System	25 Sep 2020 20:26:40

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:26:30', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '83b41de2-4cb7-45c4-8056-4a8cead9093a'	System	25 Sep 2020 20:26:40
User entered '96.9'	System	25 Sep 2020 20:26:40

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:26:33', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '83b41de2-4cb7-45c4-8056-4a8cead9093a'	System	25 Sep 2020 20:26:40
User entered 'No (N)'	System	25 Sep 2020 20:26:40



US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:26:37', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '83b41de2-4cb7-45c4-8056-4a8cead9093a'	System	25 Sep 2020 20:26:40
User entered '25 Sep 2020 16:26'	System	25 Sep 2020 20:26:40

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 5'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:50:25', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'be84721e-4157-4c03-99cb-5feab0083b33'	System	26 Sep 2020 21:50:41
User entered 'Yes (Y)'	System	26 Sep 2020 21:50:41

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:50:31', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'be84721e-4157-4c03-99cb-5feab0083b33'	System	26 Sep 2020 21:50:41
User entered '98.5'	System	26 Sep 2020 21:50:41

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:50:34', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'be84721e-4157-4c03-99cb-5feab0083b33'	System	26 Sep 2020 21:50:41
User entered 'No (N)'	System	26 Sep 2020 21:50:41

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:50:37', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'be84721e-4157-4c03-99cb-5feab0083b33'	System	26 Sep 2020 21:50:41
User entered '26 Sep 2020 17:50'	System	26 Sep 2020 21:50:41



**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 6'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:16:46', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'bf9aad68-1a2f-4a70-8497-ba11639ce8e2'	System	27 Sep 2020 22:17:05
User entered 'Yes (Y)'	System	27 Sep 2020 22:17:05

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:16:52', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'bf9aad68-1a2f-4a70-8497-ba11639ce8e2'	System	27 Sep 2020 22:17:05
User entered '97.5'	System	27 Sep 2020 22:17:05

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:16:55', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'bf9aad68-1a2f-4a70-8497-ba11639ce8e2'	System	27 Sep 2020 22:17:05
User entered 'No (N)'	System	27 Sep 2020 22:17:05

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:16:59', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'bf9aad68-1a2f-4a70-8497-ba11639ce8e2'	System	27 Sep 2020 22:17:05
User entered '27 Sep 2020 18:16'	System	27 Sep 2020 22:17:05

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:24:46



**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 7'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:18:49', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'fb9d742e-0ef6-4f1e-880f-f20deea496d0'	System	29 Sep 2020 06:20:20
User entered 'Yes (Y)'	System	29 Sep 2020 06:20:20

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:10', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'fb9d742e-0ef6-4f1e-880f-f20deea496d0'	System	29 Sep 2020 06:20:20
User entered '96.1'	System	29 Sep 2020 06:20:20

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:14', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'fb9d742e-0ef6-4f1e-880f-f20deea496d0'	System	29 Sep 2020 06:20:20
User entered 'No (N)'	System	29 Sep 2020 06:20:20

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:18', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'fb9d742e-0ef6-4f1e-880f-f20deea496d0'	System	29 Sep 2020 06:20:20
User entered '29 Sep 2020 02:20'	System	29 Sep 2020 06:20:20

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:37:49', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6f50516e-aa30-4e90-82de-edb2c28d6b3c'	System	22 Sep 2020 14:38:09
User entered 'None (1)'	System	22 Sep 2020 14:38:09

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:37:53', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6f50516e-aa30-4e90-82de-edb2c28d6b3c'	System	22 Sep 2020 14:38:09
User entered 'No (N)'	System	22 Sep 2020 14:38:09

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:37:55', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6f50516e-aa30-4e90-82de-edb2c28d6b3c'	System	22 Sep 2020 14:38:09
User entered 'No (N)'	System	22 Sep 2020 14:38:09

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:38:01', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6f50516e-aa30-4e90-82de-edb2c28d6b3c'	System	22 Sep 2020 14:38:09
User entered 'None (1)'	System	22 Sep 2020 14:38:09

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:38:07', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6f50516e-aa30-4e90-82de-edb2c28d6b3c'	System	22 Sep 2020 14:38:09
User entered '22 Sep 2020 10:38'	System	22 Sep 2020 14:38:09

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '22 Sep 2020 10:23'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '22 Sep 2020 12:53'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:48:39', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '777a1eed-e3c3-418e-a01b-f3872f8dba0b'	System	23 Sep 2020 13:49:13
User entered 'None (1)'	System	23 Sep 2020 13:49:13

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:48:53', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '777a1eed-e3c3-418e-a01b-f3872f8dba0b'	System	23 Sep 2020 13:49:13
User entered 'No (N)'	System	23 Sep 2020 13:49:13

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:48:57', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '777a1eed-e3c3-418e-a01b-f3872f8dba0b'	System	23 Sep 2020 13:49:13
User entered 'No (N)'	System	23 Sep 2020 13:49:13

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:49:07', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '777a1eed-e3c3-418e-a01b-f3872f8dba0b'	System	23 Sep 2020 13:49:13
User entered 'None (1)'	System	23 Sep 2020 13:49:13

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:49:11', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '777a1eed-e3c3-418e-a01b-f3872f8dba0b'	System	23 Sep 2020 13:49:13
User entered '23 Sep 2020 09:49'	System	23 Sep 2020 13:49:13

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '22 Sep 2020 13:48'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 2'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:09:48', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c68c218c-91dd-49a4-83cb-0bf4e0287eb2'	System	23 Sep 2020 16:10:06
User entered 'None (1)'	System	23 Sep 2020 16:10:06

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:09:50', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c68c218c-91dd-49a4-83cb-0bf4e0287eb2'	System	23 Sep 2020 16:10:06
User entered 'No (N)'	System	23 Sep 2020 16:10:06

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:09:53', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c68c218c-91dd-49a4-83cb-0bf4e0287eb2'	System	23 Sep 2020 16:10:06
User entered 'No (N)'	System	23 Sep 2020 16:10:06

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:09:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c68c218c-91dd-49a4-83cb-0bf4e0287eb2'	System	23 Sep 2020 16:10:06
User entered 'None (1)'	System	23 Sep 2020 16:10:06

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:09:58', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c68c218c-91dd-49a4-83cb-0bf4e0287eb2'	System	23 Sep 2020 16:10:06
User entered '23 Sep 2020 12:09'	System	23 Sep 2020 16:10:06

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 3'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:01', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '974355dc-fd2e-4fa8-9c0d-b8d8435ead7c'	System	24 Sep 2020 18:49:25
User entered 'None (1)'	System	24 Sep 2020 18:49:25

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:07', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '974355dc-fd2e-4fa8-9c0d-b8d8435ead7c'	System	24 Sep 2020 18:49:25
User entered 'No (N)'	System	24 Sep 2020 18:49:25

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:08', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '974355dc-fd2e-4fa8-9c0d-b8d8435ead7c'	System	24 Sep 2020 18:49:25
User entered 'No (N)'	System	24 Sep 2020 18:49:25

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:13', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '974355dc-fd2e-4fa8-9c0d-b8d8435ead7c'	System	24 Sep 2020 18:49:25
User entered 'None (1)'	System	24 Sep 2020 18:49:25

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:17', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '974355dc-fd2e-4fa8-9c0d-b8d8435ead7c'	System	24 Sep 2020 18:49:25
User entered '24 Sep 2020 14:49'	System	24 Sep 2020 18:49:25

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 4'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:26:41', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '510f549b-1cb4-4322-8a13-fe7173b8a40c'	System	25 Sep 2020 20:26:52
User entered 'None (1)'	System	25 Sep 2020 20:26:52

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:26:43', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '510f549b-1cb4-4322-8a13-fe7173b8a40c'	System	25 Sep 2020 20:26:52
User entered 'No (N)'	System	25 Sep 2020 20:26:52

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:26:45', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '510f549b-1cb4-4322-8a13-fe7173b8a40c'	System	25 Sep 2020 20:26:52
User entered 'No (N)'	System	25 Sep 2020 20:26:52

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:26:47', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '510f549b-1cb4-4322-8a13-fe7173b8a40c'	System	25 Sep 2020 20:26:52
User entered 'None (1)'	System	25 Sep 2020 20:26:52

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:26:49', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '510f549b-1cb4-4322-8a13-fe7173b8a40c'	System	25 Sep 2020 20:26:52
User entered '25 Sep 2020 16:26'	System	25 Sep 2020 20:26:52

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 5'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:50:45', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '19aba3eb-e49c-4f6e-af27-e0af05f6d534'	System	26 Sep 2020 21:51:01
User entered 'None (1)'	System	26 Sep 2020 21:51:01

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:50:48', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '19aba3eb-e49c-4f6e-af27-e0af05f6d534'	System	26 Sep 2020 21:51:01
User entered 'No (N)'	System	26 Sep 2020 21:51:01

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:50:52', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '19aba3eb-e49c-4f6e-af27-e0af05f6d534'	System	26 Sep 2020 21:51:01
User entered 'No (N)'	System	26 Sep 2020 21:51:01

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:50:54', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '19aba3eb-e49c-4f6e-af27-e0af05f6d534'	System	26 Sep 2020 21:51:01
User entered 'None (1)'	System	26 Sep 2020 21:51:01

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:50:59', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '19aba3eb-e49c-4f6e-af27-e0af05f6d534'	System	26 Sep 2020 21:51:01
User entered '26 Sep 2020 17:50'	System	26 Sep 2020 21:51:01

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 6'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:08', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '60c3ebb2-b197-4f92-ae89-e16ea9911bb1'	System	27 Sep 2020 22:17:28
User entered 'None (1)'	System	27 Sep 2020 22:17:28

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:23', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '60c3ebb2-b197-4f92-ae89-e16ea9911bb1'	System	27 Sep 2020 22:17:28
User entered 'No (N)'	System	27 Sep 2020 22:17:28

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:13', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '60c3ebb2-b197-4f92-ae89-e16ea9911bb1'	System	27 Sep 2020 22:17:28
User entered 'No (N)'	System	27 Sep 2020 22:17:28

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:15', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '60c3ebb2-b197-4f92-ae89-e16ea9911bb1'	System	27 Sep 2020 22:17:28
User entered 'None (1)'	System	27 Sep 2020 22:17:28

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:25', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '60c3ebb2-b197-4f92-ae89-e16ea9911bb1'	System	27 Sep 2020 22:17:28
User entered '27 Sep 2020 18:17'	System	27 Sep 2020 22:17:28

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 7'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:25', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e4208b45-9567-4ae3-9010-7b0cfdafd999'	System	29 Sep 2020 06:20:37
User entered 'None (1)'	System	29 Sep 2020 06:20:37

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:27', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e4208b45-9567-4ae3-9010-7b0cfdafd999'	System	29 Sep 2020 06:20:37
User entered 'No (N)'	System	29 Sep 2020 06:20:37

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:30', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e4208b45-9567-4ae3-9010-7b0cfdafd999'	System	29 Sep 2020 06:20:37
User entered 'No (N)'	System	29 Sep 2020 06:20:37

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:32', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e4208b45-9567-4ae3-9010-7b0cfdafd999'	System	29 Sep 2020 06:20:37
User entered 'None (1)'	System	29 Sep 2020 06:20:37

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:35', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e4208b45-9567-4ae3-9010-7b0cfdafd999'	System	29 Sep 2020 06:20:37
User entered '29 Sep 2020 02:20'	System	29 Sep 2020 06:20:37

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:38:13', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '18472e13-7a27-46d5-869d-ba82da38f00b'	System	22 Sep 2020 14:38:49
User entered 'No interference with activity (1)'	System	22 Sep 2020 14:38:49

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:38:23', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '18472e13-7a27-46d5-869d-ba82da38f00b'	System	22 Sep 2020 14:38:49
User entered 'None (0)'	System	22 Sep 2020 14:38:49

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:38:28', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '18472e13-7a27-46d5-869d-ba82da38f00b'	System	22 Sep 2020 14:38:49
User entered 'None (0)'	System	22 Sep 2020 14:38:49

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:38:32', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '18472e13-7a27-46d5-869d-ba82da38f00b'	System	22 Sep 2020 14:38:49
User entered 'None (0)'	System	22 Sep 2020 14:38:49

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:38:35', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '18472e13-7a27-46d5-869d-ba82da38f00b'	System	22 Sep 2020 14:38:49
User entered 'None (0)'	System	22 Sep 2020 14:38:49

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:38:37', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '18472e13-7a27-46d5-869d-ba82da38f00b'	System	22 Sep 2020 14:38:49
User entered 'None (0)'	System	22 Sep 2020 14:38:49

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:38:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '18472e13-7a27-46d5-869d-ba82da38f00b'	System	22 Sep 2020 14:38:49
User entered 'No (N)'	System	22 Sep 2020 14:38:49



US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-22T10:38:45', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '18472e13-7a27-46d5-869d-ba82da38f00b'	System	22 Sep 2020 14:38:49
User entered '22 Sep 2020 10:38'	System	22 Sep 2020 14:38:49

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '22 Sep 2020 10:23'	System	22 Sep 2020 14:24:46

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '22 Sep 2020 12:53'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:49:20', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '0112e689-b2b2-4db8-a195-72b85514e53b'	System	23 Sep 2020 13:49:53
User entered 'No interference with activity (1)'	System	23 Sep 2020 13:49:53

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:49:27', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '0112e689-b2b2-4db8-a195-72b85514e53b'	System	23 Sep 2020 13:49:53
User entered 'None (0)'	System	23 Sep 2020 13:49:53

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:49:33', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '0112e689-b2b2-4db8-a195-72b85514e53b'	System	23 Sep 2020 13:49:53
User entered 'None (0)'	System	23 Sep 2020 13:49:53

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:49:37', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '0112e689-b2b2-4db8-a195-72b85514e53b' User entered 'None (0)'	System	23 Sep 2020 13:49:53
	System	23 Sep 2020 13:49:53



US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:49:41', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '0112e689-b2b2-4db8-a195-72b85514e53b'	System	23 Sep 2020 13:49:53
User entered 'None (0)'	System	23 Sep 2020 13:49:53

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:49:43', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '0112e689-b2b2-4db8-a195-72b85514e53b'	System	23 Sep 2020 13:49:53
User entered 'None (0)'	System	23 Sep 2020 13:49:53

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:49:47', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '0112e689-b2b2-4db8-a195-72b85514e53b'	System	23 Sep 2020 13:49:53
User entered 'No (N)'	System	23 Sep 2020 13:49:53

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T09:49:49', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '0112e689-b2b2-4db8-a195-72b85514e53b'	System	23 Sep 2020 13:49:53
User entered '23 Sep 2020 09:49'	System	23 Sep 2020 13:49:53

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '22 Sep 2020 13:48'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:46:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 2'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:10:11', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd4110926-d571-488e-b2b7-27267229d008'	System	23 Sep 2020 16:10:37
User entered 'None (0)'	System	23 Sep 2020 16:10:37



US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:10:17', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd4110926-d571-488e-b2b7-27267229d008'	System	23 Sep 2020 16:10:37
User entered 'None (0)'	System	23 Sep 2020 16:10:37

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:10:20', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd4110926-d571-488e-b2b7-27267229d008'	System	23 Sep 2020 16:10:37
User entered 'None (0)'	System	23 Sep 2020 16:10:37

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:10:22', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd4110926-d571-488e-b2b7-27267229d008'	System	23 Sep 2020 16:10:37
User entered 'None (0)'	System	23 Sep 2020 16:10:37

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:10:23', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd4110926-d571-488e-b2b7-27267229d008'	System	23 Sep 2020 16:10:37
User entered 'None (0)'	System	23 Sep 2020 16:10:37

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:10:24', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd4110926-d571-488e-b2b7-27267229d008'	System	23 Sep 2020 16:10:37
User entered 'None (0)'	System	23 Sep 2020 16:10:37

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:10:27', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd4110926-d571-488e-b2b7-27267229d008'	System	23 Sep 2020 16:10:37
User entered 'No (N)'	System	23 Sep 2020 16:10:37

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-23T12:10:30', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd4110926-d571-488e-b2b7-27267229d008'	System	23 Sep 2020 16:10:37
User entered '23 Sep 2020 12:10'	System	23 Sep 2020 16:10:37

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:24:46



**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 3'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:25', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '899321ae-aaf3-4010-b13c-1f11e6fe3ccf'	System	24 Sep 2020 18:49:57
User entered 'None (0)'	System	24 Sep 2020 18:49:57

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:27', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '899321ae-aaf3-4010-b13c-1f11e6fe3ccf'	System	24 Sep 2020 18:49:57
User entered 'None (0)'	System	24 Sep 2020 18:49:57

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:29', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '899321ae-aaf3-4010-b13c-1f11e6fe3ccf'	System	24 Sep 2020 18:49:57
User entered 'None (0)'	System	24 Sep 2020 18:49:57

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:31', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '899321ae-aaf3-4010-b13c-1f11e6fe3ccf'	System	24 Sep 2020 18:49:57
User entered 'None (0)'	System	24 Sep 2020 18:49:57

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:33', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '899321ae-aaf3-4010-b13c-1f11e6fe3ccf'	System	24 Sep 2020 18:49:57
User entered 'None (0)'	System	24 Sep 2020 18:49:57

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:34', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '899321ae-aaf3-4010-b13c-1f11e6fe3ccf'	System	24 Sep 2020 18:49:57
User entered 'None (0)'	System	24 Sep 2020 18:49:57



US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:47', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '899321ae-aaf3-4010-b13c-1f11e6fe3ccf'	System	24 Sep 2020 18:49:57
User entered 'No (N)'	System	24 Sep 2020 18:49:57

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-24T14:49:49', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '899321ae-aaf3-4010-b13c-1f11e6fe3ccf'	System	24 Sep 2020 18:49:57
User entered '24 Sep 2020 14:49'	System	24 Sep 2020 18:49:57

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 4'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:26:55', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd0308788-d02a-4cbf-b9b6-c9e17b9ed03f'	System	25 Sep 2020 20:27:18
User entered 'No interference with activity (1)'	System	25 Sep 2020 20:27:18

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:27:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd0308788-d02a-4cbf-b9b6-c9e17b9ed03f'	System	25 Sep 2020 20:27:18
User entered 'No interference with activity (1)'	System	25 Sep 2020 20:27:18

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:27:02', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd0308788-d02a-4cbf-b9b6-c9e17b9ed03f'	System	25 Sep 2020 20:27:18
User entered 'None (0)'	System	25 Sep 2020 20:27:18



US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:27:04', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd0308788-d02a-4cbf-b9b6-c9e17b9ed03f'	System	25 Sep 2020 20:27:18
User entered 'None (0)'	System	25 Sep 2020 20:27:18

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:27:06', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd0308788-d02a-4cbf-b9b6-c9e17b9ed03f'	System	25 Sep 2020 20:27:18
User entered 'None (0)'	System	25 Sep 2020 20:27:18

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:27:08', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd0308788-d02a-4cbf-b9b6-c9e17b9ed03f'	System	25 Sep 2020 20:27:18
User entered 'None (0)'	System	25 Sep 2020 20:27:18

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:27:12', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd0308788-d02a-4cbf-b9b6-c9e17b9ed03f'	System	25 Sep 2020 20:27:18
User entered 'No (N)'	System	25 Sep 2020 20:27:18

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-25T16:27:14', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd0308788-d02a-4cbf-b9b6-c9e17b9ed03f'	System	25 Sep 2020 20:27:18
User entered '25 Sep 2020 16:27'	System	25 Sep 2020 20:27:18

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 5'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:51:05', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c285f23b-b63c-435e-91cd-88bc80a33452'	System	26 Sep 2020 21:51:33
User entered 'None (0)'	System	26 Sep 2020 21:51:33

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:51:08', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c285f23b-b63c-435e-91cd-88bc80a33452'	System	26 Sep 2020 21:51:33
User entered 'No interference with activity (1)'	System	26 Sep 2020 21:51:33

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:51:15', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c285f23b-b63c-435e-91cd-88bc80a33452'	System	26 Sep 2020 21:51:33
User entered 'None (0)'	System	26 Sep 2020 21:51:33

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:51:18', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c285f23b-b63c-435e-91cd-88bc80a33452'	System	26 Sep 2020 21:51:33
User entered 'None (0)'	System	26 Sep 2020 21:51:33

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:51:20', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c285f23b-b63c-435e-91cd-88bc80a33452'	System	26 Sep 2020 21:51:33
User entered 'None (0)'	System	26 Sep 2020 21:51:33

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:51:23', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c285f23b-b63c-435e-91cd-88bc80a33452'	System	26 Sep 2020 21:51:33
User entered 'None (0)'	System	26 Sep 2020 21:51:33

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:51:27', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c285f23b-b63c-435e-91cd-88bc80a33452'	System	26 Sep 2020 21:51:33
User entered 'No (N)'	System	26 Sep 2020 21:51:33

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-26T17:51:29', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'c285f23b-b63c-435e-91cd-88bc80a33452'	System	26 Sep 2020 21:51:33
User entered '26 Sep 2020 17:51'	System	26 Sep 2020 21:51:33



**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 6'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:33', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5c3a45a-c843-4485-ad62-44030890659d'	System	27 Sep 2020 22:17:54
User entered 'None (0)'	System	27 Sep 2020 22:17:54

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:36', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5c3a45a-c843-4485-ad62-44030890659d'	System	27 Sep 2020 22:17:54
User entered 'No interference with activity (1)'	System	27 Sep 2020 22:17:54

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:38', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5c3a45a-c843-4485-ad62-44030890659d' User entered 'None (0)'	System	27 Sep 2020 22:17:54
	System	27 Sep 2020 22:17:54

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:40', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5c3a45a-c843-4485-ad62-44030890659d' User entered 'None (0)'	System	27 Sep 2020 22:17:54
	System	27 Sep 2020 22:17:54

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5c3a45a-c843-4485-ad62-44030890659d' User entered 'None (0)'	System	27 Sep 2020 22:17:54
	System	27 Sep 2020 22:17:54



US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:44', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5c3a45a-c843-4485-ad62-44030890659d' User entered 'None (0)'	System	27 Sep 2020 22:17:54
	System	27 Sep 2020 22:17:54

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:47', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5c3a45a-c843-4485-ad62-44030890659d'	System	27 Sep 2020 22:17:54
User entered 'No (N)'	System	27 Sep 2020 22:17:54

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-27T18:17:50', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5c3a45a-c843-4485-ad62-44030890659d'	System	27 Sep 2020 22:17:54
User entered '27 Sep 2020 18:17'	System	27 Sep 2020 22:17:54

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	22 Sep 2020 14:24:46
User entered 'Day 7'	System	22 Sep 2020 14:24:46

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:39', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51dd23e8-a56e-49f9-81a8-a6c8421e9fa7'	System	29 Sep 2020 06:20:59
User entered 'None (0)'	System	29 Sep 2020 06:20:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51dd23e8-a56e-49f9-81a8-a6c8421e9fa7'	System	29 Sep 2020 06:20:59
User entered 'No interference with activity (1)'	System	29 Sep 2020 06:20:59



US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:44', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51dd23e8-a56e-49f9-81a8-a6c8421e9fa7'	System	29 Sep 2020 06:20:59
User entered 'None (0)'	System	29 Sep 2020 06:20:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:47', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51dd23e8-a56e-49f9-81a8-a6c8421e9fa7'	System	29 Sep 2020 06:20:59
User entered 'None (0)'	System	29 Sep 2020 06:20:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:48', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51dd23e8-a56e-49f9-81a8-a6c8421e9fa7'	System	29 Sep 2020 06:20:59
User entered 'None (0)'	System	29 Sep 2020 06:20:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:51', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51dd23e8-a56e-49f9-81a8-a6c8421e9fa7'	System	29 Sep 2020 06:20:59
User entered 'None (0)'	System	29 Sep 2020 06:20:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:53', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51dd23e8-a56e-49f9-81a8-a6c8421e9fa7'	System	29 Sep 2020 06:20:59
User entered 'No (N)'	System	29 Sep 2020 06:20:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-29T02:20:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51dd23e8-a56e-49f9-81a8-a6c8421e9fa7'	System	29 Sep 2020 06:20:59
User entered '29 Sep 2020 02:20'	System	29 Sep 2020 06:20:59

US3482094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:46:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:24:46

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:24:46



US3482094

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:46:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
Data entry locked.	System	27 Sep 2020 22:17:54
User entered 'Day 8'	System	27 Sep 2020 22:17:54

US3482094

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:46:24

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-30T00:38:10', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '438e92bd-e3ae-414d-b758-c481e6a48403'	System	30 Sep 2020 04:38:16
User entered 'None (0)'	System	30 Sep 2020 04:38:16

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-30T00:38:14', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '438e92bd-e3ae-414d-b758-c481e6a48403'	System	30 Sep 2020 04:38:16
User entered '30 Sep 2020 00:38'	System	30 Sep 2020 04:38:16

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 22:17:54

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:38
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 22:17:54

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	27 Sep 2020 22:17:54
User entered 'Day 8'	System	27 Sep 2020 22:17:54

US3482094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:46:24

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-30T00:38:20', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8d127174-b252-4f03-88d6-172926d5c95c'	System	30 Sep 2020 04:38:24
User entered 'No (N)'	System	30 Sep 2020 04:38:24

US3482094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:46:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-09-30T00:38:23', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8d127174-b252-4f03-88d6-172926d5c95c'	System	30 Sep 2020 04:38:24
User entered '30 Sep 2020 00:38'	System	30 Sep 2020 04:38:24



**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 22:17:54

**US3482094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:46:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 22:17:54

**US3482094**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:06:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	29 Sep 2020 19:48:05

**US3482094**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:06:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '29 Sep 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	29 Sep 2020 19:48:05

**US3482094**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:06:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	29 Sep 2020 19:48:05

US3482094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:46:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:06:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4)	29 Sep 2020 19:48:05

US3482094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	29 Sep 2020 19:48:10

**US3482094**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'I'	System	29 Sep 2020 19:48:10



**US3482094**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:03:44
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	07 Oct 2020 17:56:27

**US3482094**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:03:44
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '6 Oct 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	07 Oct 2020 17:56:27

US3482094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:46:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:03:44
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	07 Oct 2020 17:56:27

US3482094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:46:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:03:44
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4)	07 Oct 2020 17:56:27

US3482094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:03:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	07 Oct 2020 17:56:34

**US3482094**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'I'	System	07 Oct 2020 17:56:34

**US3482094**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:22:44

**US3482094**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '14 Oct 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:22:44



**US3482094**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:22:44

**US3482094**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4)	22 Oct 2020 20:22:44

US3482094

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:44
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:22:49

**US3482094**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'I'	System	22 Oct 2020 20:22:49

**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:42:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:27:29

**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:42:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '22 Oct 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:27:29

**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:42:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Clinic (Clinic)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:27:29

**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'VISIT3'	System	22 Oct 2020 20:27:29



US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'No (N)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:30

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:30

**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:30

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered empty.	System	22 Oct 2020 20:28:30

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:30

**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:30

**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:30

**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:30



**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered empty.	System	22 Oct 2020 20:28:30

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:30

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered empty.	System	22 Oct 2020 20:28:30

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:30

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered empty.	System	22 Oct 2020 20:28:30

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered empty.	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:30

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered empty.	System	22 Oct 2020 20:28:30

US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48



US3482094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48

US3482094

(b)

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:34:45
User closed query 'Source document says physical exam was not conducted. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:32:48
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Query 'Source document says physical exam was not conducted. Please verify and update.' answered with 'Updated to reflect source.' (Site from CRA).	Michelle Wiles (b) (4)	16 Apr 2021 14:40:13
Signature has been broken.	Michelle Wiles (b) (4)	16 Apr 2021 14:38:08
User entered 'No (N)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	16 Apr 2021 14:38:08
User opened query 'Source document says physical exam was not conducted. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:48:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	Geoffrey Kamau (b) (4)	22 Oct 2020 20:28:48

US3482094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:34:45
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	16 Apr 2021 14:38:08
User entered empty; reason for change Data Entry Error	(b) (4) Michelle Wiles (b) (4)	16 Apr 2021 14:38:08
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4) System	22 Oct 2020 20:28:54
User entered '22 Oct 2020' reason for change: Data Entry Error	Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:54
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	22 Oct 2020 20:28:48
User entered empty.	Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:28:48

US3482094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:29:19

US3482094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '22 Oct 2020'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:29:19

**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:46:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered '10:18'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:29:19

**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered '22 Oct 2020 10:18'	System	22 Oct 2020 20:29:19

US3482094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:48:18
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:19:46
User entered 'Yes (Y)'	(b) (4) Geoffrey Kamau (b) (4) (b) (4)	22 Oct 2020 20:29:26



**US3482094**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'I'	System	22 Oct 2020 20:29:26

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 64'	System	20 Aug 2020 14:38:37

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23



US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23
Data entry locked.	System	20 Aug 2020 14:38:37
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 14:38:37

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:31:23
Data entry locked.	System	20 Aug 2020 14:38:37
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 71'	System	20 Aug 2020 14:38:37

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-10-27T01:46:35', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6816deb1-d063-4164-8e24-88b143c0bb42'	System	27 Oct 2020 05:46:48
User entered 'No (N)'	System	27 Oct 2020 05:46:48

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-10-27T01:46:40', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6816deb1-d063-4164-8e24-88b143c0bb42'	System	27 Oct 2020 05:46:48
User entered 'No (N)'	System	27 Oct 2020 05:46:48



**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-10-27T01:46:45', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '6816deb1-d063-4164-8e24-88b143c0bb42' User entered '27 Oct 2020 01:46:45'	System	27 Oct 2020 05:46:48
	System	27 Oct 2020 05:46:48

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	20 Aug 2020 14:38:37
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	20 Aug 2020 14:38:37
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 78'	System	20 Aug 2020 14:38:37

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-05T08:05:27', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '874adbaa-55d7-4d9c-a492-95d7a2313c64'	System	05 Nov 2020 13:06:08
User entered 'Yes (Y)'	System	05 Nov 2020 13:06:08

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-05T08:05:34', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '874adbaa-55d7-4d9c-a492-95d7a2313c64'	System	05 Nov 2020 13:06:08
User entered 'No (N)'	System	05 Nov 2020 13:06:08

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-05T08:05:52', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '874adbaa-55d7-4d9c-a492-95d7a2313c64'	System	05 Nov 2020 13:06:08
User entered 'No (N)'	System	05 Nov 2020 13:06:08

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-05T08:05:57', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '874adbaa-55d7-4d9c-a492-95d7a2313c64'	System	05 Nov 2020 13:06:08
User entered 'No (N)'	System	05 Nov 2020 13:06:08



**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-05T08:06:01', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '874adbaa-55d7-4d9c-a492-95d7a2313c64'	System	05 Nov 2020 13:06:08
User entered '05 Nov 2020 08:06:01'	System	05 Nov 2020 13:06:08

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	20 Aug 2020 14:38:37
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	20 Aug 2020 14:38:37
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	20 Aug 2020 14:38:37
User entered 'Day 92'	System	20 Aug 2020 14:38:37

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-17T10:27:06', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '89c51864-b279-4289-a354-bc5c141e9f42'	System	17 Nov 2020 15:27:26
User entered 'No (N)'	System	17 Nov 2020 15:27:26

US3482094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:46:24

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-17T10:27:09', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '89c51864-b279-4289-a354-bc5c141e9f42'	System	17 Nov 2020 15:27:26
User entered 'Yes (Y)'	System	17 Nov 2020 15:27:26

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-17T10:27:13', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '89c51864-b279-4289-a354-bc5c141e9f42'	System	17 Nov 2020 15:27:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 15:27:26

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-17T10:27:17', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '89c51864-b279-4289-a354-bc5c141e9f42'	System	17 Nov 2020 15:27:26
User entered '17 Nov 2020 10:27:17'	System	17 Nov 2020 15:27:26



**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	20 Aug 2020 14:38:37
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:16:41
Data entry locked.	System	20 Aug 2020 14:38:37
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 14:38:37

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (0a404f58b79c9890)', Time: '2020-11-22T10:35:34', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7b864e94-43c6-4ebf-9f42-cd1215f2e2e5'	System	22 Nov 2020 15:36:12
User entered 'No (N)'	System	22 Nov 2020 15:36:12

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Have you been exposed to someone with 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 (0a404f58b79c9890)', Time: '2020-11-22T10:35:47', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7b864e94-43c6-4ebf-9f42-cd1215f2e2e5'	System	22 Nov 2020 15:36:12
User entered 'Yes (Y)'	System	22 Nov 2020 15:36:12

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Please 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 (0a404f58b79c9890)', Time: '2020-11-22T10:35:52', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7b864e94-43c6-4ebf-9f42-cd1215f2e2e5'	System	22 Nov 2020 15:36:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 15:36:12

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-22T10:36:01', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7b864e94-43c6-4ebf-9f42-cd1215f2e2e5'	System	22 Nov 2020 15:36:12
User entered '22 Nov 2020 10:36:01'	System	22 Nov 2020 15:36:12

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (0a404f58b79c9890)', Time: '2020-11-28T06:48:03', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e36cbf14-b960-4482-b925-14b0cf218d82'	System	28 Nov 2020 11:48:13
User entered 'No (N)'	System	28 Nov 2020 11:48:13

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Have you been exposed to someone with 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 (0a404f58b79c9890)', Time: '2020-11-28T06:48:07', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e36cbf14-b960-4482-b925-14b0cf218d82'	System	28 Nov 2020 11:48:13
User entered 'No (N)'	System	28 Nov 2020 11:48:13

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a404f58b79c9890)', Time: '2020-11-28T06:48:11', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e36cbf14-b960-4482-b925-14b0cf218d82'	System	28 Nov 2020 11:48:13
User entered '28 Nov 2020 06:48:11'	System	28 Nov 2020 11:48:13

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2020-12-09T10:34:36', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '5e945363-9a23-425d-b087-60fee01fb590'	System	09 Dec 2020 15:34:45
User entered 'No (N)'	System	09 Dec 2020 15:34:45

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2020-12-09T10:34:39', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '5e945363-9a23-425d-b087-60fee01fb590'	System	09 Dec 2020 15:34:45
User entered 'No (N)'	System	09 Dec 2020 15:34:45

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-09T10:34:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '5e945363-9a23-425d-b087-60fee01fb590'	System	09 Dec 2020 15:34:45
User entered '09 Dec 2020 10:34:42'	System	09 Dec 2020 15:34:45

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:18', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered 'Yes (Y)'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:25', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered 'No (N)'	System	16 Dec 2020 18:03:29



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:30', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered 'Yes (Y)'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '0'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '0'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '0'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '1'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '0'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '1'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '1'	System	16 Dec 2020 18:03:29



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '1'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '1'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '1'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '0'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '1'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '1'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '1'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '0'	System	16 Dec 2020 18:03:29



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '0'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:02:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '0'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Please 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 (590c886fa6bd3ff1)', Time: '2020-12-16T13:03:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2020-12-16T13:03:06', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered 'Yes (Y)'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Please 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 (590c886fa6bd3ff1)', Time: '2020-12-16T13:03:10', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-16T13:03:16', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '733f0761-3fd2-4823-836b-a09ad74e1c2c'	System	16 Dec 2020 18:03:29
User entered '16 Dec 2020 13:03:16'	System	16 Dec 2020 18:03:29

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2020-12-19T05:21:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '069812b8-85e0-481f-a57b-8dbe674fdb2b'	System	19 Dec 2020 10:21:59
User entered 'No (N)'	System	19 Dec 2020 10:21:59

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2020-12-19T05:21:51', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '069812b8-85e0-481f-a57b-8dbe674fdb2b'	System	19 Dec 2020 10:21:59
User entered 'No (N)'	System	19 Dec 2020 10:21:59

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-19T05:21:56', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '069812b8-85e0-481f-a57b-8dbe674fdb2b'	System	19 Dec 2020 10:21:59
User entered '19 Dec 2020 05:21:56'	System	19 Dec 2020 10:21:59

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2020-12-26T09:56:21', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '32a5b10d-dcb6-4937-bee4-43800bb93a20'	System	26 Dec 2020 14:56:35
User entered 'No (N)'	System	26 Dec 2020 14:56:35



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2020-12-26T09:56:29', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '32a5b10d-dcb6-4937-bee4-43800bb93a20'	System	26 Dec 2020 14:56:35
User entered 'No (N)'	System	26 Dec 2020 14:56:35

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2020-12-26T09:56:32', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '32a5b10d-dcb6-4937-bee4-43800bb93a20'	System	26 Dec 2020 14:56:35
User entered '26 Dec 2020 09:56:32'	System	26 Dec 2020 14:56:35

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-01-02T23:10:15', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51335972-e821-4e00-800a-af30e6745d6f'	System	03 Jan 2021 04:29:38
User entered 'No (N)'	System	03 Jan 2021 04:29:38

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-01-02T23:10:20', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51335972-e821-4e00-800a-af30e6745d6f'	System	03 Jan 2021 04:29:38
User entered 'No (N)'	System	03 Jan 2021 04:29:38

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-01-02T23:10:22', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '51335972-e821-4e00-800a-af30e6745d6f' User entered '02 Jan 2021 23:10:22'	System	03 Jan 2021 04:29:38
	System	03 Jan 2021 04:29:38



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-01-12T15:58:04', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'f79ed3d9-9ddb-44df-b3f1-3ee2d7f069f5'	System	12 Jan 2021 20:58:38
User entered 'No (N)'	System	12 Jan 2021 20:58:38

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-01-12T15:58:33', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'f79ed3d9-9ddb-44df-b3f1-3ee2d7f069f5'	System	12 Jan 2021 20:58:38
User entered 'No (N)'	System	12 Jan 2021 20:58:38

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-01-12T15:58:35', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'f79ed3d9-9ddb-44df-b3f1-3ee2d7f069f5'	System	12 Jan 2021 20:58:38
User entered '12 Jan 2021 15:58:35'	System	12 Jan 2021 20:58:38

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-01-17T09:53:32', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e21c48eb-f01e-4ebc-8eac-60e6ec2cafb4'	System	17 Jan 2021 14:53:41
User entered 'No (N)'	System	17 Jan 2021 14:53:41

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-01-17T09:53:34', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e21c48eb-f01e-4ebc-8eac-60e6ec2cafb4'	System	17 Jan 2021 14:53:41
User entered 'No (N)'	System	17 Jan 2021 14:53:41

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-01-17T09:53:36', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'e21c48eb-f01e-4ebc-8eac-60e6ec2cafb4'	System	17 Jan 2021 14:53:41
User entered '17 Jan 2021 09:53:36'	System	17 Jan 2021 14:53:41

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-01-23T00:02:32', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '816d0daf-696e-47bc-8d61-83cb5ec59666'	System	23 Jan 2021 05:03:18
User entered 'No (N)'	System	23 Jan 2021 05:03:18



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-01-23T00:02:39', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '816d0daf-696e-47bc-8d61-83cb5ec59666'	System	23 Jan 2021 05:03:18
User entered 'No (N)'	System	23 Jan 2021 05:03:18

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-01-23T00:02:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '816d0daf-696e-47bc-8d61-83cb5ec59666'	System	23 Jan 2021 05:03:18
User entered '23 Jan 2021 00:02:42'	System	23 Jan 2021 05:03:18

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-01-30T08:55:04', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '2e1c871c-5ec2-483b-8a68-ad1bb408fee0'	System	30 Jan 2021 13:55:18
User entered 'No (N)'	System	30 Jan 2021 13:55:18

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-01-30T08:55:07', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '2e1c871c-5ec2-483b-8a68-ad1bb408fee0'	System	30 Jan 2021 13:55:18
User entered 'No (N)'	System	30 Jan 2021 13:55:18

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-01-30T08:55:15', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '2e1c871c-5ec2-483b-8a68-ad1bb408fee0'	System	30 Jan 2021 13:55:18
User entered '30 Jan 2021 08:55:15'	System	30 Jan 2021 13:55:18



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-02-06T00:33:35', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'dd38ed6d-050b-482f-b0c1-10fae50ca90b'	System	06 Feb 2021 05:33:48
User entered 'No (N)'	System	06 Feb 2021 05:33:48

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-02-06T00:33:37', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'dd38ed6d-050b-482f-b0c1-10fae50ca90b'	System	06 Feb 2021 05:33:48
User entered 'No (N)'	System	06 Feb 2021 05:33:48

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-02-06T00:33:42', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'dd38ed6d-050b-482f-b0c1-10fae50ca90b'	System	06 Feb 2021 05:33:48
User entered '06 Feb 2021 00:33:42'	System	06 Feb 2021 05:33:48

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-02-13T00:50:22', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '87268193-c5da-4491-ad26-3edc5268f0b3'	System	13 Feb 2021 05:50:35
User entered 'No (N)'	System	13 Feb 2021 05:50:35

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-02-13T00:50:26', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '87268193-c5da-4491-ad26-3edc5268f0b3'	System	13 Feb 2021 05:50:35
User entered 'No (N)'	System	13 Feb 2021 05:50:35

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-02-13T00:50:29', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '87268193-c5da-4491-ad26-3edc5268f0b3'	System	13 Feb 2021 05:50:35
User entered '13 Feb 2021 00:50:29'	System	13 Feb 2021 05:50:35

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-02-20T19:02:27', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'dcac4e25-4230-4f6f-8111-af099a3a66fe'	System	21 Feb 2021 00:06:25
User entered 'No (N)'	System	21 Feb 2021 00:06:25



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-02-20T19:02:31', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'dcac4e25-4230-4f6f-8111-af099a3a66fe'	System	21 Feb 2021 00:06:25
User entered 'No (N)'	System	21 Feb 2021 00:06:25

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-02-20T19:02:33', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'dcac4e25-4230-4f6f-8111-af099a3a66fe' User entered '20 Feb 2021 19:02:33'	System	21 Feb 2021 00:06:25

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-02-27T09:54:14-05:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'aaf3a7e6-9132-4f33-8458-389e7b2ff82c'	System	27 Feb 2021 14:54:24
User entered 'No (N)'	System	27 Feb 2021 14:54:24

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-02-27T09:54:17-05:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'aaf3a7e6-9132-4f33-8458-389e7b2ff82c'	System	27 Feb 2021 14:54:24
User entered 'No (N)'	System	27 Feb 2021 14:54:24

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-02-27T09:54:20-05:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'aaf3a7e6-9132-4f33-8458-389e7b2ff82c' User entered '27 Feb 2021 09:54:20'	System	27 Feb 2021 14:54:24
	System	27 Feb 2021 14:54:24



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-03-07T18:51:49-05:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '235b1c22-96da-4148-ac6b-21d82ff5d7d3'	System	07 Mar 2021 23:52:00
User entered 'No (N)'	System	07 Mar 2021 23:52:00

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-03-07T18:51:53-05:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '235b1c22-96da-4148-ac6b-21d82ff5d7d3'	System	07 Mar 2021 23:52:00
User entered 'No (N)'	System	07 Mar 2021 23:52:00

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-03-07T18:51:57-05:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '235b1c22-96da-4148-ac6b-21d82ff5d7d3'	System	07 Mar 2021 23:52:00
User entered '07 Mar 2021 18:51:57'	System	07 Mar 2021 23:52:00

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-03-14T23:31:31-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a59c2a8-0637-427a-8923-c6b0f0d1c484'	System	15 Mar 2021 03:32:04
User entered 'No (N)'	System	15 Mar 2021 03:32:04

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-03-14T23:31:57-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a59c2a8-0637-427a-8923-c6b0f0d1c484'	System	15 Mar 2021 03:32:04
User entered 'No (N)'	System	15 Mar 2021 03:32:04

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-03-14T23:31:59-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '8a59c2a8-0637-427a-8923-c6b0f0d1c484' User entered '14 Mar 2021 23:31:59'	System	15 Mar 2021 03:32:04
	System	15 Mar 2021 03:32:04

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-03-20T23:47:29-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'f045f680-df76-4cb7-80ad-5fcb7948f2d8'	System	21 Mar 2021 03:47:49
User entered 'No (N)'	System	21 Mar 2021 03:47:49



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-03-20T23:47:43-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'f045f680-df76-4cb7-80ad-5fcb7948f2d8'	System	21 Mar 2021 03:47:49
User entered 'No (N)'	System	21 Mar 2021 03:47:49

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-03-20T23:47:46-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'f045f680-df76-4cb7-80ad-5fcb7948f2d8'	System	21 Mar 2021 03:47:49
User entered '20 Mar 2021 23:47:46'	System	21 Mar 2021 03:47:49

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-03-27T17:44:53-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd43b7155-b03c-4cbd-a237-ce78398e6bf9' User entered 'No (N)'	System	27 Mar 2021 21:45:12
	System	27 Mar 2021 21:45:12

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-03-27T17:45:06-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd43b7155-b03c-4cbd-a237-ce78398e6bf9' User entered 'No (N)'	System	27 Mar 2021 21:45:12
	System	27 Mar 2021 21:45:12

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-03-27T17:45:09-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd43b7155-b03c-4cbd-a237-ce78398e6bf9' User entered '27 Mar 2021 17:45:09'	System	27 Mar 2021 21:45:12
	System	27 Mar 2021 21:45:12



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-04-03T13:53:38-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'a48893db-eddf-4e4e-a038-63f4f454e4d7'	System	03 Apr 2021 17:53:50
User entered 'No (N)'	System	03 Apr 2021 17:53:50

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-04-03T13:53:42-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'a48893db-eddf-4e4e-a038-63f4f454e4d7'	System	03 Apr 2021 17:53:50
User entered 'No (N)'	System	03 Apr 2021 17:53:50

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-03T13:53:45-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'a48893db-eddf-4e4e-a038-63f4f454e4d7'	System	03 Apr 2021 17:53:50
User entered '03 Apr 2021 13:53:45'	System	03 Apr 2021 17:53:50

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-04-13T10:33:47-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5e28556-cd3b-43ba-b155-0cb904e32ee4' User entered 'No (N)'	System	13 Apr 2021 14:33:55
	System	13 Apr 2021 14:33:55

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-04-13T10:33:49-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5e28556-cd3b-43ba-b155-0cb904e32ee4'	System	13 Apr 2021 14:33:55
User entered 'No (N)'	System	13 Apr 2021 14:33:55

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-13T10:33:52-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: 'd5e28556-cd3b-43ba-b155-0cb904e32ee4'	System	13 Apr 2021 14:33:55
User entered '13 Apr 2021 10:33:52'	System	13 Apr 2021 14:33:55

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-04-18T23:29:34-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '48a51d03-001b-4c5b-8b62-5a98771dae7a' User entered 'No (N)'	System	19 Apr 2021 03:29:43
	System	19 Apr 2021 03:29:43



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-04-18T23:29:38-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '48a51d03-001b-4c5b-8b62-5a98771dae7a'	System	19 Apr 2021 03:29:43
User entered 'No (N)'	System	19 Apr 2021 03:29:43

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-18T23:29:40-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '48a51d03-001b-4c5b-8b62-5a98771dae7a'	System	19 Apr 2021 03:29:43
User entered '18 Apr 2021 23:29:40'	System	19 Apr 2021 03:29:43

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-04-24T08:55:47-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered 'Yes (Y)'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Have you been exposed to someone with 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 (590c886fa6bd3ff1)', Time: '2021-04-24T08:55:51-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered 'No (N)'	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-04-24T08:55:58-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered 'Yes (Y)'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '1'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '1'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '1'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:10-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '0'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Please 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 (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:20-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd'	System	24 Apr 2021 13:14:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[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 (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:29-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered 'No (N)'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-04-24T08:56:32-04:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7795f30e-49db-46a7-9379-280fb58f9dcd' User entered '24 Apr 2021 08:56:32'	System	24 Apr 2021 13:14:26
	System	24 Apr 2021 13:14:26

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:31:23



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:31:23



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:31:23

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:31:23



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:31:23



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:31:23



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:31:23

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:31:23

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:31:23

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:31:23



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:31:23



**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:31:23

**US3482094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:46:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:31:23
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:31:23



US3482094

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:46:24**

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)	26 Apr 2021 13:15:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-02-27T09:54:04-05:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7eeee7b1-0e3d-4bff-aebe-ceae03acb4f2'	System	27 Feb 2021 14:54:15
User entered 'No (N)'	System	27 Feb 2021 14:54:15

**US3482094**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:15:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590c886fa6bd3ff1)', Time: '2021-02-27T09:54:08-05:00', User OID: 'PatientReportedOutcome (US3482094)', ODM File OID: '7eeee7b1-0e3d-4bff-aebe-ceae03acb4f2'	System	27 Feb 2021 14:54:15
User entered '27 Feb 2021 09:54:08'	System	27 Feb 2021 14:54:15

**US3482094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:20:47

**US3482094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:20:47

**US3482094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:20:47

US3482094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:46:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:20:47

**US3482094**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:22:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:20:54

**US3482094**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:48
User entered 'I'	System	19 Nov 2020 19:20:54



**US3482094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	Amy Anderson (b) (4)	21 Dec 2020 20:52:02

**US3482094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '18 Dec 2020'	Amy Anderson (b) (4)	21 Dec 2020 20:52:02

**US3482094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Anderson (b) (4)	21 Dec 2020 20:52:02

**US3482094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	Amy Anderson (b) (4)	21 Dec 2020 20:52:02

**US3482094**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	Amy Anderson (b) (4)	21 Dec 2020 20:52:17

**US3482094**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered 'I'	System	21 Dec 2020 20:52:17

**US3482094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:52:05

**US3482094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:52:05



**US3482094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:52:05

**US3482094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:52:05

US3482094

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:52:18

**US3482094**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered 'I'	System	19 Jan 2021 14:52:18

**US3482094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 03:17:48

**US3482094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 03:17:48

**US3482094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 03:17:48

**US3482094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 03:17:48



US3482094

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 03:18:12

**US3482094**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered 'I'	System	20 Feb 2021 03:18:12

US3482094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	11 Mar 2021 17:57:06

1b

**US3482094**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '11 Mar 2021'	(b) (4) Sarah Bechnak (b) (4)	11 Mar 2021 17:57:06

US3482094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[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 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Clinic (Clinic)'	(b) (4) Sarah Bechnak (b) (4)	11 Mar 2021 17:57:06

**US3482094**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered 'VISIT4'	System	11 Mar 2021 17:57:06

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	Mari Hart (b) (4)	31 Mar 2021 21:10:31

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 21:10:31



US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 21:10:31

**US3482094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered empty.	System	31 Mar 2021 21:10:31

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 21:10:31

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 21:10:31

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 21:10:31

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 21:10:31

**US3482094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered empty.	System	31 Mar 2021 21:10:31

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 21:10:31



US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered empty.	System	31 Mar 2021 21:10:31

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 21:10:31

**US3482094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered empty.	System	31 Mar 2021 21:10:31

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	Mari Hart (b) (4)	31 Mar 2021 21:10:31

**US3482094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered empty.	System	31 Mar 2021 21:10:31

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47

US3482094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47

US3482094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	15 Mar 2021 20:29:41
User entered 'No (N)' reason for change: Data Entry Error	System	15 Mar 2021 20:29:27
User entered 'Yes (Y)'	Sarah Bechnak (b) (4)	15 Mar 2021 20:29:27
	(b) (4)	
	Sarah Bechnak (b) (4)	11 Mar 2021 17:58:20
	(b) (4)	



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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sarah Bechnak (b) (4)	15 Mar 2021 20:29:41
User entered '11 Mar 2021'	(b) (4)	
	Sarah Bechnak (b) (4)	11 Mar 2021 17:58:20
	(b) (4)	

US3482094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Mar 2021 19:01:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	11 Mar 2021 19:01:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	11 Mar 2021 19:01:44
	Sarah Bechnak (b) (4)	11 Mar 2021 19:01:44
	(b) (4)	

US3482094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '11 Mar 2021'	(b) (4) Sarah Bechnak (b) (4)	11 Mar 2021 19:01:44
	(b) (4)	

US3482094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '11:25'	(b) (4) Sarah Bechnak (b) (4)	11 Mar 2021 19:01:44

**US3482094**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered '11 Mar 2021 11:25'	System	11 Mar 2021 19:01:44

US3482094

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) Sarah Bechnak (b) (4)	11 Mar 2021 19:01:53

**US3482094**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:37:47
User entered 'I'	System	11 Mar 2021 19:01:53

**US3482094**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:23:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:44:33



**US3482094**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:23:10
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:44:33

**US3482094**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:23:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:44:33

**US3482094**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:46:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:23:10
User entered '4/20/21: left voicemail and sent email'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:44:33

US3482094

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:46:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	23 Apr 2021 03:23:10
User entered 'Yes (Y)'	Amy Anderson (b) (4) (b) (4)	21 Apr 2021 17:24:52

**US3482094**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 17:24:52

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:35
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:45:32
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:01:46
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'SALIVA COLLECTION INFO VERIFIED IN DCF.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:54:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:16:54
User entered '13 Oct 2020'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:36:51

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:35
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:45:41
User entered '08:40'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:36:51

**US3482094**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:46:24**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:35
User entered '13 Oct 2020 08:40'	System	13 Oct 2020 13:36:51



US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:35
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:45:55
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:36:51

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:35
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:45:57
User entered 'Yes (Y)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:36:51

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Day 1 (Day 1)'	Tiffany Lee (b) (4)	13 Oct 2020 13:40:54
	(b) (4)	

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:29
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '11 Oct 2020' reason for change: New Information	(b) (4)	
	Tiffany Lee (b) (4)	25 Nov 2020 20:42:16
User entered '10 Oct 2020'	(b) (4)	
	Tiffany Lee (b) (4)	13 Oct 2020 13:40:54
	(b) (4)	

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:31
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:56:48
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:11:00
User entered '0' reason for change: Per Query Resolution	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:10:48
User opened query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:04:14
User entered '1' reason for change: New Information	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16
User entered '0'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:27
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: If O2 Saturation and Temperature were not recorded, please enter them as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 11:06:51
Query 'Per CDM: If O2 Saturation and Temperature were not recorded, please enter them as Not Done.' answered with 'done' (Site from DM).	Amy Anderson (b) (4) (b) (4)	20 Jan 2021 19:35:42
User entered missing code ND - Not Done; reason for change New Information	Amy Anderson (b) (4) (b) (4)	20 Jan 2021 19:35:36
User opened query 'Per CDM: If O2 Saturation and Temperature were not recorded, please enter them as Not Done.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 14:49:21
User entered empty; reason for change New Information	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16
User entered '96'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User entered '%'	System	20 Jan 2021 19:35:36
User entered empty.	System	25 Nov 2020 20:42:16
User entered '%'	System	13 Oct 2020 13:40:54

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:58:15
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:32:18
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:32:18
User entered '100.0' F reason for change: New Information	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:32:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 20:12:25
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered missing code ND - Not Done; reason for change New Information	Amy Anderson (b) (4)	20 Jan 2021 19:35:36
	(b) (4)	
User entered empty; reason for change New Information	Tiffany Lee (b) (4)	25 Nov 2020 20:42:16
	(b) (4)	
User entered '98.4' F	Tiffany Lee (b) (4)	13 Oct 2020 13:40:54
	(b) (4)	



US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:35:09
User closed query 'Source document has note that list chills as a symptom. Please verify and update. All symptoms noted in source do not list any severity information. Please review this with patient and update source and EDC as needed.' (Site from CRA). Query 'Source document has note that list chills as a symptom. Please verify and update. All symptoms noted in source do not list any severity information. Please review this with patient and update source and EDC as needed.' answered with 'updated per source' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:35:02
User entered 'Moderate (Moderate)' reason for change: Data Entry Error Signature has been broken.	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 16:20:58
	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 16:06:22
	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 16:03:56
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 16:03:56
User opened query 'Source document has note that list chills as a symptom. Please verify and update. All symptoms noted in source do not list any severity information. Please review this with patient and update source and EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 20:15:23
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 20:14:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:23
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:35:11
User closed query 'Source documentation does not indicate severity of symptoms. Please include source documentation of this and update as needed.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:35:01
Query 'Source documentation does not indicate severity of symptoms. Please include source documentation of this and update as needed.' answered with 'updated per source' (Site from CRA).	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 16:21:20
Signature has been broken.	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 16:06:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 16:06:22
User opened query 'Source documentation does not indicate severity of symptoms. Please include source documentation of this and update as needed.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 20:13:14
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Moderate (Moderate)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:31:04
User closed query 'Muscle Aches are not listed on the source document only body aches. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:29:45
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Query 'Muscle Aches are not listed on the source document only body aches. Please verify and update accordingly.' answered with 'removed' (Site from CRA).	Amy Anderson (b) (4)	16 Apr 2021 17:22:13
Signature has been broken.	Amy Anderson (b) (4)	16 Apr 2021 17:21:51
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	16 Apr 2021 17:21:51
User opened query 'Muscle Aches are not listed on the source document only body aches. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Moderate (Moderate)'	Tiffany Lee (b) (4)	13 Oct 2020 13:40:54

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:35:27
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Moderate (Moderate)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:36:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Moderate (Moderate)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:31:15
User closed query 'Please verify severity based on late entry note dated 16Apr21.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:29:58
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Query 'Please verify severity based on late entry note dated 16Apr21.' answered with 'updating to moderate' (Site from CRA).	Amy Anderson (b) (4)	16 Apr 2021 17:22:45
Signature has been broken.	Amy Anderson (b) (4)	16 Apr 2021 17:22:34
User entered 'Moderate (Moderate)' reason for change: Per Query Resolution	Amy Anderson (b) (4)	16 Apr 2021 17:22:34
User opened query 'Please verify severity based on late entry note dated 16Apr21.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:36:53
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:36:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:36:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	Tiffany Lee (b) (4)	13 Oct 2020 13:40:54

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:31:27
User closed query 'Please verify severity based on late entry note date 16Apr21.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:30:12
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Query 'Please verify severity based on late entry note date 16Apr21.' answered with 'updating to moderate' (Site from CRA).	Amy Anderson (b) (4)	16 Apr 2021 17:22:54
Signature has been broken.	Amy Anderson (b) (4)	16 Apr 2021 17:21:51
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amy Anderson (b) (4)	16 Apr 2021 17:21:51
User opened query 'Please verify severity based on late entry note date 16Apr21.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:37:43
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	Tiffany Lee (b) (4)	13 Oct 2020 13:40:54

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Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:12:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:40:54

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:31:39
User closed query 'Please verify severity with late entry note dated 16Apr21 and update as needed.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:30:33
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Query 'Please verify severity with late entry note dated 16Apr21 and update as needed.' answered with 'updated to moderate' (Site from CRA).	Amy Anderson (b) (4)	16 Apr 2021 17:23:14
Signature has been broken.	Amy Anderson (b) (4)	16 Apr 2021 17:21:51
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Amy Anderson (b) (4)	16 Apr 2021 17:21:51
User opened query 'Please verify severity with late entry note dated 16Apr21 and update as needed.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:38:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	Tiffany Lee (b) (4)	13 Oct 2020 13:40:54



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Form: Symptom Log (2)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Day 2 (Day 2)'	Tiffany Lee (b) (4)	25 Nov 2020 20:42:16
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:39:28
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '12 Oct 2020'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:39:08
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:56:53
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:11:29
User entered '0' reason for change: Per Query Resolution	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:11:23
User opened query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:04:57
User entered '1'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:39:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: If O2 Saturation and Temperature were not recorded, please enter them as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 11:06:59
Query 'Per CDM: If O2 Saturation and Temperature were not recorded, please enter them as Not Done.' answered with 'done' (Site from DM).	Amy Anderson (b) (4) (b) (4)	20 Jan 2021 19:36:13
User entered missing code ND - Not Done; reason for change Per Query Resolution	Amy Anderson (b) (4) (b) (4)	20 Jan 2021 19:36:04
User opened query 'Per CDM: If O2 Saturation and Temperature were not recorded, please enter them as Not Done.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 14:49:47
User entered empty.	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User entered '%'	System	20 Jan 2021 19:36:04
User entered empty.	System	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:41:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	20 Jan 2021 19:36:04
User entered empty.	Tiffany Lee (b) (4)	25 Nov 2020 20:42:16
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'None (None)'	Tiffany Lee (b) (4)	25 Nov 2020 20:42:16
	(b) (4)	

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Form: Symptom Log (2)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Mild (Mild)'	Tiffany Lee (b) (4)	25 Nov 2020 20:42:16
	(b) (4)	



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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Moderate (Moderate)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Moderate (Moderate)'	Tiffany Lee (b) (4)	25 Nov 2020 20:42:16
	(b) (4)	

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Moderate (Moderate)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Moderate (Moderate)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16



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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Mild (Mild)'	Tiffany Lee (b) (4)	25 Nov 2020 20:42:16
	(b) (4)	

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Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Mild (Mild)'	Tiffany Lee (b) (4)	25 Nov 2020 20:42:16
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:42:16

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Form: Symptom Log (2)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:36:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Mild (Mild)'	Tiffany Lee (b) (4)	25 Nov 2020 20:42:16
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
	(b) (4)	
User entered 'Day 4 (Day 4)' reason for change:	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
Data Entry Error	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Day 3 (Day 3)'	Tiffany Lee (b) (4)	25 Nov 2020 20:45:03
	(b) (4)	

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:56:19
User entered '13 Oct 2020'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:56:22
User entered '0'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:56:17
User entered '96'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User entered '%'	System	25 Nov 2020 20:45:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:56:24
User entered '98.4' F	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:56:27
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:56:29
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:56:31
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:56:33
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:56:54
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:56:59
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:57:08
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:57:12
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:57:16
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:57:19
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:57:29
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:57:31
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:57:33
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:57:37
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:57:38
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:57:41
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:45:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Day 4 (Day 4)'	Tiffany Lee (b) (4)	25 Nov 2020 20:47:50
	(b) (4)	

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:59:37
User entered '14 Oct 2020'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:59:39
User entered '0'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:59:41
User entered '98'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User entered '%'	System	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:59:43
User entered '99.2' F	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:59:55
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:00:01
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:00:13
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:04:08
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:04:11
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:04:18
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:04:26
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:04:30
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:04:45
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:04:47
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:04:53
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:04:58
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:05:02
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:05:05
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:05:07
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:05:12
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:47:50

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
	(b) (4)	
User entered 'Day 6 (Day 6)' reason for change:	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
Data Entry Error	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Day 5 (Day 5)'	Tiffany Lee (b) (4)	25 Nov 2020 20:50:03
	(b) (4)	

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:09:23
User entered '15 Oct 2020'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:09:24
User entered '0'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

**US3482094**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:46:24**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:09:27
User entered '97'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

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**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:46:24**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User entered '%'	System	25 Nov 2020 20:50:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:09:29
User entered '98.6' F	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:09:33
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:09:40
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:09:44
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:09:55
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:10:03
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:45:46
User closed query 'Per source, patient had mild muscles aches. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:45:40
Query 'Per source, patient had mild muscles aches. Please confirm and update.' answered with 'CORRECT.' (Site from CRA).	(b) (4), (b) (6)	15 Jan 2021 00:03:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:12:18
User opened query 'Per source, patient had mild muscles aches. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 18:12:14
DataPoint Un-verified.	(b) (4), (b) (6)	23 Dec 2020 18:10:14
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 18:10:06
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:45:48
User closed query 'Per source, patient had body muscles aches. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:45:42
Query 'Per source, patient had body muscles aches. Please confirm and update.' answered with 'CORRECT.' (Site from CRA).	(b) (4), (b) (6)	15 Jan 2021 00:03:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:12:18
User opened query 'Per source, patient had body muscles aches. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 18:12:29
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:12:34
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:12:38
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:12:40
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:12:44
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:12:48
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:12:52
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:12:55
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:12:58
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:13:01
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:50:03



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
Signature has been broken.	(b) (4)	
	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Amy Anderson (b) (4)	16 Apr 2021 17:30:42
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
	(b) (4)	
User entered 'Day 6 (Day 6)'	Tiffany Lee (b) (4)	25 Nov 2020 20:52:18
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:28:24
User entered '16 Oct 2020'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:28:32
User entered '0'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:28:35
User entered '98'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User entered '%'	System	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:28:37
User entered '98.0' F	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:28:42
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:28:46
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:28:48
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:28:52
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:29:02
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:29:04
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:29:07
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:29:31
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:29:34
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:29:36
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:29:39
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:29:56
User entered 'Mild (Mild)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:29:58
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:46:12
User closed query 'Per source, patient had no vomiting on this date.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:46:09
Query 'Per source, patient had no vomiting on this date.' answered with 'CORRECTED.' (Site from CRA).	(b) (4), (b) (6)	15 Jan 2021 00:05:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 00:05:34
User opened query 'Per source, patient had no vomiting on this date.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 18:33:28
User entered empty.	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:30:01
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:30:04
User entered 'None (None)'	Tiffany Lee (b) (4) (b) (4)	25 Nov 2020 20:52:18

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'Day 1 (Day 1)'	(b) (4) Amy Anderson (b) (4)	16 Apr 2021 17:30:20

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered '10 Oct 2020'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered '0'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered missing code ND - Not Done.	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

**US3482094**

**Folder: Covid-19 Assessment 13 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:46:24**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
User entered '%'	System	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered missing code ND - Not Done.	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'Moderate (Moderate)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'Moderate (Moderate)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20



US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'Moderate (Moderate)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'Moderate (Moderate)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'Moderate (Moderate)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'Moderate (Moderate)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'Moderate (Moderate)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20



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Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:38
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:59:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
User entered 'Moderate (Moderate)'	(b) (4) Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:30:20

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:34:24
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 13 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:30:49
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 13 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:50:21
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 13 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 05:47:58
User entered '13 Oct 2020'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:41:31

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:34:24
User entered 'Yes (Y)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:41:31

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:34:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 20:22:34
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 19:04:48
Query 'Data is required. Please complete.' answered with 'No test results at this time. Participant tested today.' (Site from System).	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:42:37
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 13:41:31
User entered empty.	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:41:31

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:34:24
User entered '13 Oct 2020'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:41:31



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Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:34:24
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:41:31

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:34:24
User entered empty.	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:41:31

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:34:24
User entered 'No (N)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:41:31

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:34:24
User entered empty.	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:41:31

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:34:24
User entered empty.	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 13:41:31

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:42
User entered '0'	System	23 Nov 2020 19:04:48

US3482094

Folder: Covid-19 Assessment 13 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:46:24

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:34:36
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:54:52

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:51:52
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:45:38



US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	05 Jan 2021 15:13:20
User closed query 'Per source, time of contact was at 10:31. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 15:13:18
Query 'Per source, time of contact was at 10:31. Please confirm and update.' answered with 'updated' (Site from CRA).	Amy Anderson (b) (4)	27 Dec 2020 14:50:10
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	27 Dec 2020 14:49:56
User entered '10:31' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	27 Dec 2020 14:49:56
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 18:51:52
User opened query 'Per source, time of contact was at 10:31. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 18:50:39
User entered '10:30'	Joy Winters (b) (4)	18 Dec 2020 22:45:38
	(b) (4)	

**US3482094**

**Folder: Covid-19 Assessment 17 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:46:24**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:09
User entered '17 Dec 2020 10:31'	System	27 Dec 2020 14:49:56
User entered '17 Dec 2020 10:30'	System	18 Dec 2020 22:45:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:51:52
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:45:38

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Form: COVID-19 Contact

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[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:51:52
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:45:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 1 (Day 1)'	Joy Winters (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '09 Dec 2020' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered '10 Dec 2020'	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:33:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4)	
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 12:58:06
DataPoint Un-verified.	Amy Anderson (b) (4)	08 Jan 2021 15:13:08
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Amy Anderson (b) (4)	08 Jan 2021 15:13:02
	(b) (4)	
User opened query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:10:35
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '1' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
	(b) (4)	
User entered '0'	Joy Winters (b) (4)	18 Dec 2020 22:49:23
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	18 Dec 2020 23:00:21
User entered empty.	System	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '99' F reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 22:49:23
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23



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Form: Symptom Log (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:00:21
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:49:23

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 2 (Day 2)'	Joy Winters (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '10 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:32:01
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4)	
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 12:58:22
DataPoint Un-verified.	Amy Anderson (b) (4)	08 Jan 2021 15:13:35
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Amy Anderson (b) (4)	08 Jan 2021 15:13:29
	(b) (4)	
User opened query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:11:54
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '1'	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	18 Dec 2020 23:19:02
User entered empty.	System	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 23:19:11
User entered '99' F reason for change: Data Entry Error	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:19:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 23:19:02
User entered '99' (non-conformant).	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:19:02
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 3 (Day 3)'	Joy Winters (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '11 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (3)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:34:03
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate. '(Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:58:39
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate. ' answered with 'updated' (Site from DM).	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:14:09
DataPoint Un-verified.	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:13:54
User entered '0' reason for change: Per Query Resolution	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:13:54
User opened query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate. '(Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:12:11
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '1'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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**Folder: Covid-19 Assessment 17 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:46:24**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	18 Dec 2020 23:19:02
User entered empty.	System	18 Dec 2020 23:03:50

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (3)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (3)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (3)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (3)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (3)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 4 (Day 4)'	Joy Winters (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '12 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:40:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:58:44
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate. answered with 'updated' (Site from DM).	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:14:44
DataPoint Un-verified.	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:14:38
User entered '0' reason for change: Per Query Resolution	Amy Anderson (b) (4) (b) (4)	08 Jan 2021 15:14:38
User opened query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate. (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:13:08
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '1'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	18 Dec 2020 23:19:02
User entered empty.	System	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 5 (Day 5)'	Joy Winters (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '13 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:40:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4)	
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:54:28
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	Amy Anderson (b) (4)	15 Jan 2021 17:50:58
	(b) (4)	
DataPoint Un-verified.	Amy Anderson (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Amy Anderson (b) (4)	15 Jan 2021 17:50:51
	(b) (4)	
User opened query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:17:53
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '1'	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	18 Dec 2020 23:19:02
User entered empty.	System	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 6 (Day 6)'	Joy Winters (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '14 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:40:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4)	
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:54:36
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	Amy Anderson (b) (4)	15 Jan 2021 17:51:22
	(b) (4)	
DataPoint Un-verified.	Amy Anderson (b) (4)	15 Jan 2021 17:51:18
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Amy Anderson (b) (4)	15 Jan 2021 17:51:18
	(b) (4)	
User opened query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:18:54
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '1'	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:19:02
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	18 Dec 2020 23:19:02
User entered empty.	System	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	



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Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (6)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 7 (Day 7)'	Joy Winters (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '15 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:41:03
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4)	
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:54:44
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	Amy Anderson (b) (4)	15 Jan 2021 17:51:37
	(b) (4)	
DataPoint Un-verified.	Amy Anderson (b) (4)	15 Jan 2021 17:51:31
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Amy Anderson (b) (4)	15 Jan 2021 17:51:31
	(b) (4)	
User opened query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:19:53
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '1'	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	18 Dec 2020 23:19:02
User entered empty.	System	18 Dec 2020 23:03:50

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Form: Symptom Log (7)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	



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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (7)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (7)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (7)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (7)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (7)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 8 (Day 8)'	Joy Winters (b) (4)	18 Dec 2020 23:03:50

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '16 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:41:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4)	
Query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:54:59
DataPoint Un-verified.	Amy Anderson (b) (4)	15 Jan 2021 17:51:54
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Amy Anderson (b) (4)	15 Jan 2021 17:51:49
	(b) (4)	
User opened query 'Per CDM: Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:20:51
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '1'	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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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)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	18 Dec 2020 23:19:02
User entered empty.	System	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:19:02
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:26:46
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (8)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Form: Symptom Log (8)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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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)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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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)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:32:34
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 9 (Day 9)'	Joy Winters (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:01
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:03
User entered '0'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:08
User entered '99' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	18 Dec 2020 23:24:29
User entered empty.	System	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:06
User entered '98.5' F reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:14
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:23
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:22:27
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:22:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:32
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:37
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:53
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:55
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:22:58
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (9)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:23:02
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:24:29
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 10 (Day 10)'	Joy Winters (b) (4)	18 Dec 2020 23:03:50

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Form: Symptom Log (10)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:23:31
User entered '18 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:23:33
User entered '0'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:23:36
User entered '99' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:26:30
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	18 Dec 2020 23:26:30
User entered empty.	System	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:23:37
User entered '98.2' F reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:26:30
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:23:40
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:23:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:23:46
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:23:57
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:24:01
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:03:50
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:07
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:09
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:19
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:21
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:24
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:26
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:28
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:30:40
User entered empty.	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:03:50



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 11 (Day 11)'	Mary Bower (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:50
User entered '19 Dec 2020'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:52
User entered '0'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:54
User entered '96'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:56
User entered '101' F	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:24:58
User entered 'Moderate (Moderate)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:25:00
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:25:02
User entered 'Mild (Mild)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:25:04
User entered 'Mild (Mild)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:25:07
User entered 'Moderate (Moderate)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:25:11
User entered 'Mild (Mild)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:25:13
User entered 'Moderate (Moderate)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:25:16
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:25:21
User entered 'Mild (Mild)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:13:45
User closed query 'Per source, patient had mild symptoms of new loss of smell. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 15:13:43
Query 'Per source, patient had mild symptoms of new loss of smell. Please confirm and update.' answered with 'corrected' (Site from CRA).	Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:37:16
DataPoint Un-verified.	Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:37:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:37:09
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:28:22
User opened query 'Per source, patient had mild symptoms of new loss of smell. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 19:25:59
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16



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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:03
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:06
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:08
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:10
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:12
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:13
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:24:16

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 12 (Day 12)'	Mary Bower (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:27
User entered '20 Dec 2020'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:29
User entered '0'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:32
User entered '94'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:33
User entered '101.5' F	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:37
User entered 'Mild (Mild)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:40
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:42
User entered 'Mild (Mild)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:44
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:46
User entered 'Moderate (Moderate)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:48
User entered 'Moderate (Moderate)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:49
User entered 'Moderate (Moderate)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:52
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:56
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:26:58
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:00
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:01
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:03
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:05
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:07
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:09
User entered 'None (None)'	Mary Bower (b) (4) (b) (4)	20 Dec 2020 23:35:11

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 13 (Day 13)'	(b) (4) Amy Anderson (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:21
User entered '21 Dec 2020'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:23
User entered '0'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:25
User entered '98'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:27
User entered '100.7' F	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:29
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:31
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:36
User entered 'Moderate (Moderate)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:40
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:42
User entered 'Moderate (Moderate)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:44
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:45
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:47
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:55
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:57
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:27:59
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:01
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:04
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:06
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41



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Form: Symptom Log (13)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:11
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Form: Symptom Log (13)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:14
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 19:02:41

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Form: Symptom Log (14)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 14 (Day 14)'	(b) (4) Michelle Wiles (b) (4)	23 Dec 2020 17:11:13

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Form: Symptom Log (14)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '22 Dec 2020'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '0'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '98'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	23 Dec 2020 17:11:13

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '103.0' F	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13



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Form: Symptom Log (14)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Severe (Severe)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Form: Symptom Log (14)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:11:13



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 15 (Day 15)'	(b) (4) Michelle Wiles (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '23 Dec 2020'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '0'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 01:18:23
User entered '94' reason for change: New Information	Amy Anderson (b) (4)	27 Dec 2020 18:38:06
DataPoint Un-verified.	(b) (4) Michelle Wiles (b) (4)	24 Dec 2020 17:37:26
User entered '944' reason for change: New Information	Michelle Wiles (b) (4)	24 Dec 2020 17:37:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '94'	Michelle Wiles (b) (4)	23 Dec 2020 17:15:18
	(b) (4)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered '103.5' F	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:28:22
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:15:18

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 16 (Day 16)'	(b) (4) Michelle Wiles (b) (4)	24 Dec 2020 16:00:04

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:39:14
User entered '24 Dec 2020'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:39:16
User entered '0'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:38:16
User entered '97' reason for change: New Information	Michelle Wiles (b) (4)	24 Dec 2020 17:37:26
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	24 Dec 2020 17:37:26
User entered empty.	System	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:38:13
User entered '103.3' F reason for change: New Information	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 17:37:26
User entered '100.9' F	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:39:25
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:39:28
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:40:24
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:40:26
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:40:30
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:40:37
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:40:39
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:40:41
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:40:56
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:40:57
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:40:59
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:41:03
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:41:06
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:41:08
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:41:10
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:41:11
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:00:04

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 18 (Day 18)'	(b) (4) Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:46:20
User entered '26 Dec 2020'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:46:21
User entered '0'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:09
User entered '95'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:12
User entered '98.4' F	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:13
User entered 'None (None)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:16
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:20
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:21
User entered 'None (None)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:25
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:27
User entered 'None (None)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:29
User entered 'None (None)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:32
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:44
User entered 'None (None)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:47
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:50
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:47:57
User entered 'None (None)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:48:01
User entered 'None (None)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:48:06
User entered 'None (None)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:48:11
User entered 'None (None)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (17)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:48:13
User entered 'None (None)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:22:38

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 19 (Day 19)'	(b) (4) Amy Anderson (b) (4)	27 Dec 2020 18:38:06

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:24:54
User entered '27 Dec 2020'	Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:24:58
User entered '0'	Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:25:02
User entered '93'	Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	27 Dec 2020 18:38:06

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:25:11
User entered '98.2' F reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:25:13
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:46:41
User closed query 'Per source, patient had mild symptoms of cough on this date. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:46:38
Query 'Per source, patient had mild symptoms of cough on this date. Please confirm and update.' answered with 'updated' (Site from CRA).	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:53:26
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:53:19
User opened query 'Per source, patient had mild symptoms of cough on this date. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 20:29:39
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:39:32
User entered empty.	Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:29:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:29:48
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:29:51
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:29:54
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:29:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:29:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:30:14
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:30:16
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:31:03
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:31:04
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:31:08
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:31:09
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:31:11
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:31:13
User entered 'None (None)' reason for change: Data Entry Error	Amy Anderson (b) (4)	27 Dec 2020 18:39:32
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:38:06



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 17 (Day 17)'	(b) (4) Michelle Wiles (b) (4)	29 Dec 2020 16:21:35

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:53
User entered '25 Dec 2020'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:57
User entered '0'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:59
User entered '93'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:00
User entered '98.7' F	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:04
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:06
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35



US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:08
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:10
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:18
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:19
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:21
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:26
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:38
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:39
User entered 'Moderate (Moderate)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:44
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:43:47
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:44:43
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:44:46
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:44:48
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:44:50
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	29 Dec 2020 16:21:35

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 20 (Day 20)'	(b) (4) Amy Anderson (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:37:14
User entered '28 Dec 2020'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03



US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:37:42
User entered '0'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:37:44
User entered '96'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:37:46
User entered '99.5' F	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:01
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:03
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:05
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:07
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:10
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:13
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:15
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:17
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:39:33
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:39:35
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:39:38
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:39:41
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:39:43
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:39:45
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:39:46
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:39:48
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:06:03

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 21 (Day 21)'	Amy Anderson (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:41:38
User entered '29 Dec 2020'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:41:40
User entered '0'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:41:49
User entered '94'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:41:54
User entered '102.0' F	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:41:57
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:41:59
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:42:00
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:42:06
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:42:10
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:42:12
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:42:14
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:42:15
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:43:32
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:43:34
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:43:40
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:43:42
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:43:46
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:43:50
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:43:52
User entered 'None (None)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:43:53
User entered 'Mild (Mild)'	Amy Anderson (b) (4) (b) (4)	29 Dec 2020 18:07:46

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 22 (Day 22)'	(b) (4) Lauren Hewitt (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:48:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '30 Dec 2020'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:48:58
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '0'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '96'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:02
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '99.5' F	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:08
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:22
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56



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Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:27
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Form: Symptom Log (22)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Form: Symptom Log (22)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Form: Symptom Log (22)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:49:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:09:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:11:45
User closed query 'Per source patient had mild sore throat. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:11:43
Query 'Per source patient had mild sore throat. Please verify and update as needed.' answered with 'corrected' (Site from CRA).	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:50:28
Signature has been broken.	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:50:04
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:50:04
User opened query 'Per source patient had mild sore throat. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:50:06
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:36:56



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 23 (Day 23)'	(b) (4) Lauren Hewitt (b) (4)	02 Jan 2021 12:41:49

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:50:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '31 Dec 2020'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '0'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:50:50
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '95'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	02 Jan 2021 12:41:49

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Form: Symptom Log (23)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:50:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '100.0' F	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:46:24

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:05
User closed query 'Source document is blank for this symptom. Please verify and complete form for this symptom.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:12:01
Query 'Source document is blank for this symptom. Please verify and complete form for this symptom.' answered with 'updated source per notes in comments' (Site from CRA).	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:54:41
User opened query 'Source document is blank for this symptom. Please verify and complete form for this symptom.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:54:41
Query 'Source document does not indicate none or any other severity level please verify if patient had chills or not and indicate on source document.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:53:52
User opened query 'Source document does not indicate none or any other severity level please verify if patient had chills or not and indicate on source document.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 14:50:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:50:55
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Form: Symptom Log (23)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:52:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49



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Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:52:20
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:46:24

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:11
User closed query 'Source document is not completed for this symptom. Please verify and complete on form for review.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:12:09
Query 'Source document is not completed for this symptom. Please verify and complete on form for review.' answered with 'updated source per notes in comments' (Site from CRA).	Amy Anderson (b) (4) (b) (4)	16 Apr 2021 17:55:01
User opened query 'Source document is not completed for this symptom. Please verify and complete on form for review.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:53:17
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Form: Symptom Log (23)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:22
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Form: Symptom Log (23)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Form: Symptom Log (23)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:25
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Form: Symptom Log (23)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:27
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (23)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Form: Symptom Log (23)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49



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Form: Symptom Log (23)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Form: Symptom Log (23)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:53:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Lauren Hewitt (b) (4) (b) (4)	02 Jan 2021 12:41:49

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Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 24 (Day 24)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:09:11
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 14:59:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:59:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Per sponsor review, please confirm date. ' (Site from DM).	(b) (4)	08 Mar 2021 09:39:16
Query 'Per CDM: Per sponsor review, please confirm date. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	
DataPoint Un-verified.	Amy Anderson (b) (4)	05 Mar 2021 20:32:28
	(b) (4)	
	Amy Anderson (b) (4)	05 Mar 2021 20:32:21
	(b) (4)	
User entered '01 Jan 2021' reason for change: Data Entry Error	Amy Anderson (b) (4)	05 Mar 2021 20:32:21
	(b) (4)	
User opened query 'Per CDM: Per sponsor review, please confirm date. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 01:10:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:46:06
	(b) (4), (b) (6)	
User entered '01 Jan 2020'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	



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Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:46:08
User entered '0'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:46:17
User entered '96'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	05 Jan 2021 00:24:44

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:46:18
User entered '98.5' F	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:46:21
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:46:23
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:46:27
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:04
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:06
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:08
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:09
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:11
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:14
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:19
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:21
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:22
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:24
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:25
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:27
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:28
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:24:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 25 (Day 25)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:09:22
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Per sponsor review, please confirm date. ' (Site from DM).	(b) (4)	
Query 'Per CDM: Per sponsor review, please confirm date. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 09:39:21
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	05 Mar 2021 20:32:57
	(b) (4)	
	Amy Anderson (b) (4)	05 Mar 2021 20:32:51
	(b) (4)	
User entered '02 Jan 2021' reason for change: Data Entry Error	Amy Anderson (b) (4)	05 Mar 2021 20:32:51
	(b) (4)	
User opened query 'Per CDM: Per sponsor review, please confirm date. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 01:10:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:47:40
	(b) (4), (b) (6)	
User entered '02 Jan 2020'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:47:42
User entered '0'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:48:41
User entered '95'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:48:43
User entered '97.8' F	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:48:45
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:48:47
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:48:49
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:48:50
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:48:56
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:48:58
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:49:00
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:49:03
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:49:11
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:49:15
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:49:17
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:49:19
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:50:01
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:50:04
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:50:05
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:50:06
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 26 (Day 26)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:09:31
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per CDM: Per sponsor review, please confirm date. ' (Site from DM).	(b) (4)	
Query 'Per CDM: Per sponsor review, please confirm date. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 09:39:25
DataPoint Un-verified.	Amy Anderson (b) (4)	05 Mar 2021 20:33:37
	(b) (4)	
	Amy Anderson (b) (4)	05 Mar 2021 20:33:23
	(b) (4)	
User entered '03 Jan 2021' reason for change: Data Entry Error	Amy Anderson (b) (4)	05 Mar 2021 20:33:23
	(b) (4)	
User opened query 'Per CDM: Per sponsor review, please confirm date. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 01:10:31
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:51:00
User entered '03 Jan 2020'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:51:01
User entered '0'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:51:05
User entered '97'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:51:06
User entered '97.9' F	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34



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Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:09:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:51:34
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:51:36
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:51:37
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:51:42
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

US3482094

Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:51:44
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:51:46
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:51:48
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:53:52
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:53:54
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:53:58
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:54:00
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:54:01
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:54:03
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:54:04
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:54:06
User entered 'None (None)'	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 27 (Day 27)' reason for change:	(b) (4)	
Data Entry Error	Amy Anderson (b) (4)	05 Jan 2021 20:33:44
User entered empty.	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:54:46
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 20:33:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 20:33:44
User entered '04 Jan 2021' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 00:28:34
User entered empty.	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:09:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '98' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
User entered empty.	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	07 Jan 2021 20:04:49
User entered empty.	System	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '97.9' F reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:12
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34



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Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:20
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:43
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (27)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:50
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:51
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Form: Symptom Log (27)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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Form: Symptom Log (27)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:10:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Amy Anderson (b) (4)	07 Jan 2021 20:04:49
	(b) (4)	
	Hollie Macenczak (b) (4)	05 Jan 2021 00:28:34

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 28 (Day 28)'	(b) (4) Amy Anderson (b) (4)	05 Jan 2021 20:33:44

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '05 Jan 2021'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44



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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:02
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '0'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:03
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '97'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
User entered '%'	System	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '98.6' F	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:08
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44



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Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:18
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:20
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:22
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:27
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:29
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:11:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:29
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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Form: Symptom Log (28)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:12:35
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Amy Anderson (b) (4) (b) (4)	05 Jan 2021 20:33:44

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[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:07:07
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:05:13

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Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:07:07
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 18:19:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 18:19:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:19:28
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 23:05:13
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:05:13

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[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:07:07
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)	22 Dec 2020 10:42:15
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 'OK' (Site from System).	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:19:47
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 18:19:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 18:19:28
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	21 Dec 2020 18:19:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:19:28
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 23:05:13
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:05:13

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:07:07
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:05:13



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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:07:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:05:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:07:07
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:05:13

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Form: COVID Diagnostic Test

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:07:07
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 18:19:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 18:19:28
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:19:28
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 23:05:13
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:05:13

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:07:07
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:05:13

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Folder: Covid-19 Assessment 17 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:07:07
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:05:13

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:16
User entered 'I'	System	21 Dec 2020 18:19:28

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:46:24

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:52:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:46:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:52:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07



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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:52:27
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:52:29
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:46:24

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:52:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:46:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:52:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:52:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:52:35
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:53:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:53:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '25 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07



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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:53:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '27 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:53:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '93'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:53:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:53:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:53:27
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:53:29
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:28
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07



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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	21 Jan 2021 18:33:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 18:33:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:33:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 18:33:07
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:34
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07



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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:50
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:51
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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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)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07



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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:01
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:03
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:51:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07



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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:18
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

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Folder: Covid-19 Assessment 17 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:46:24

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07



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Folder: Covid-19 Assessment 17 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:46:24

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:33:07

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:00:08
User entered '17 Nov 2020'	Hollie Macenczak (b) (4)	18 Nov 2020 20:56:30

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:00:08
User entered '17:00'	Hollie Macenczak (b) (4)	18 Nov 2020 20:56:30

**US3482094**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:46:24**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:56
User entered '17 Nov 2020 17:00'	System	18 Nov 2020 20:56:30

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:00:08
User entered 'Safety Call (Safety Call)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:56:30

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Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:46:24

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:00:08
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:56:30

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 1 (Day 1)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:55
User closed query 'I am unable to locate documentation of symptoms for 16Nov in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:08:51
Query 'I am unable to locate documentation of symptoms for 16Nov in source document. Please verify and update accordingly.' answered with 'there are here on a progress note.' (Site from CRA).	Amy Anderson (b) (4)	16 Apr 2021 17:45:55
User opened query 'I am unable to locate documentation of symptoms for 16Nov in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 20:24:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 18:12:23
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:03:13
User entered '16 Nov 2020'	Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:25
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User entered '%'	System	18 Nov 2020 20:58:13

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:24
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:27
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:29
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:31
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:32
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:33
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:43
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13



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Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:50
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:51
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:53
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:10:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:58:13

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 2 (Day 2)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:12:37
User entered '17 Nov 2020'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:12:39
User entered '0'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:12:40
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User entered '%'	System	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:12:42
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:12:44
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:12:46
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:13:12
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:13:14
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:13:50
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:14:58
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:01
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:03
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:21
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:19
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:17
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:15
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:13
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:11
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:09
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:07
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	18 Nov 2020 20:59:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 3 (Day 3)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:32:52
User entered '18 Nov 2020'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:21
User entered '0'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:24
User entered '98' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	18 Nov 2020 21:02:10
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:46:24**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User entered '%'	System	18 Nov 2020 21:00:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Nov 2020 21:02:26
User entered '98.3' F reason for change: Data Entry Error	Hollie Macenczak (b) (4)	18 Nov 2020 21:02:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Nov 2020 21:02:10
User entered '98.3' (non-conformant).	Hollie Macenczak (b) (4)	18 Nov 2020 21:02:10
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:27
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:47
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:46
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:44
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:43
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:41
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:39
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:51
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:34:59
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:35:01
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:35:06
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:35:08
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:35:10
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:35:14
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:35:16
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:35:17
User entered 'None (None)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:00:56



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 4 (Day 4)'	(b) (4) Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:18
User entered '19 Nov 2020'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:20
User entered '0'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:23
User entered '98'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User entered '%'	System	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:24
User entered '98.5' F	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:26
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:30
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:32
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:33
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:35
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:36
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:40
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:37:09
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:37:20
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:37:22
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:37:24
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:37:25
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:37:27
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:37:28
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:37:30
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:37:32
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 5 (Day 5)'	(b) (4) Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:37:45
User entered '20 Nov 2020'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:13
User entered '0'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:15
User entered '98'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User entered '%'	System	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:16
User entered '97.6' F	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:21
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:23
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:25
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:27
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:29
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:31
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:36
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:40:38
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:46:04
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:46:08
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:46:24
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:46:27
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



**US3482094**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:46:59
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:48:45
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:48:47
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:48:49
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 6 (Day 6)'	(b) (4) Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

**US3482094**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:26
User entered '21 Nov 2020'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:29
User entered '0'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:33
User entered '98'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User entered '%'	System	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:51:34
User entered '98.9' F	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:37
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:51:38
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:40
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:41
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:43
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:51:44
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:46
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:47
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:49
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:52
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:54
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:55
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:51:57
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:51:58
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:52:00
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:52:01
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 7 (Day 7)'	(b) (4) Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:13
User entered '22 Nov 2020'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:14
User entered '0'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:17
User entered '99'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User entered '%'	System	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:19
User entered '98.4' F	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:21
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:22
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:24
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:25
User entered 'None (None)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:28
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:30
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:31
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:34
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:35
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:38
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:53
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:56:18
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:56:19
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:56:21
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:56:22
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:56:24
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:24:28



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Day 8 (Day 8)'	(b) (4) Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

**US3482094**

**Folder: Covid-19 Assessment 17 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:46:24**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:56:52
User entered '23 Nov 2020'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:56:56
User entered '0'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:56:57
User entered '98'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User entered '%'	System	23 Nov 2020 15:53:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:56:59
User entered '98.3' F	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:00
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:02
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:04
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:08
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:57:11
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:13
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:15
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:20
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:18
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:23
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43



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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:24
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:26
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:27
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:30
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:31
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:46:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:33
User entered 'None (None)'	Hollie Macenczak (b) (4)	23 Nov 2020 15:53:43

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:27:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '18 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 21:02:59

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:06
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 21:02:59



US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 11:40:21
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 19:20:49
Query 'Data is required. Please complete.' answered with 'RESULTS PENDING' (Site from System).	Hollie Macenczak (b) (4)	18 Nov 2020 21:03:06
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 21:02:59
User entered empty.	Hollie Macenczak (b) (4)	18 Nov 2020 21:02:59

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:40
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '18 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 21:02:59

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:42
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 21:02:59

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:44
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4)	
	Hollie Macenczak (b) (4)	18 Nov 2020 21:02:59

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 21:02:59

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	18 Nov 2020 21:02:59

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered empty.	(b) (4)	
	Hollie Macenczak (b) (4)	18 Nov 2020 21:02:59

US3482094

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:46:24

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:20:02
User entered '0'	System	23 Nov 2020 19:20:49



**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered '15 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27



**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:49:27

US3482094

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:46:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 18:49:27

**US3482094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 18:46:54
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:49:27

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Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:46:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

**US3482094**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:44
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

**US3482094**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:44
User entered '20 Nov 2020'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19



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Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:46:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

**US3482094**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:10:44
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

**US3482094**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:10:44
User entered '22 Nov 2020'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

US3482094

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:46:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

US3482094

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:46:24

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:10:44
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 16:03:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 16:03:27
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	25 Nov 2020 16:03:27
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 14:29:19
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

**US3482094**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:44
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

US3482094

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:46:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

US3482094

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:46:24

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:10:44
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 16:03:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 16:03:27
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	25 Nov 2020 16:03:27
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 14:29:19
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19



**US3482094**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:44
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

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Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:46:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

US3482094

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:46:24

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:44
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 16:03:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 16:03:27
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	25 Nov 2020 16:03:27
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 14:29:19
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

**US3482094**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:44
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

US3482094

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:46:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

US3482094

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:46:24

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:10:44
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 16:03:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 16:03:27
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	25 Nov 2020 16:03:27
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 14:29:19
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

**US3482094**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:44
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

US3482094

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:46:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19



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Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:46:24

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:10:44
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 16:03:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 16:03:27
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	25 Nov 2020 16:03:27
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 14:29:19
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

**US3482094**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:10:44
User entered empty.	Hollie Macenczak (b) (4)	23 Nov 2020 14:29:19

**US3482094**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:17:07

**US3482094**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User entered 'Yes (Y)'	Mary Bower (b) (4)	19 Dec 2020 22:17:07
	(b) (4)	

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**Folder: Illness Visit (3)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User entered '19 Dec 2020'	Mary Bower (b) (4)	19 Dec 2020 22:17:07
	(b) (4)	

**US3482094**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:17:07

US3482094

Folder: Illness Visit (3)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:46:24

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:20:49
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 18:59:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 18:59:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:59:41
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Dec 2020 22:17:07
User entered empty.	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:17:07

**US3482094**

**Folder: Illness Visit (3)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:20:49
User entered '21 Dec 2020' reason for change: Data Entry Error	Amy Anderson (b) (4)	21 Dec 2020 18:59:41
User entered empty.	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:17:07



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Folder: Illness Visit (3)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:46:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:17:07

US3482094

Folder: Illness Visit (3)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:46:24

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User entered 'Yes (Y)' reason for change: New Information	Michelle Wiles (b) (4)	23 Dec 2020 17:04:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 05:57:54
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	21 Dec 2020 18:59:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Dec 2020 22:17:07
User entered empty.	Mary Bower (b) (4)	19 Dec 2020 22:17:07
	(b) (4)	

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Folder: Illness Visit (3)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:46:24

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 06:39:54
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'sample was collected on 12/23' (Site from DM).	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:39:40
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 08:33:42
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User entered '23 Dec 2020' reason for change: New Information	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:04:57
User entered empty.	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:17:07

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Folder: Illness Visit (3)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:46:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:17:07

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Folder: Illness Visit (3)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:46:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:56
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:40:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:40:02
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 05:57:59
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	21 Dec 2020 19:00:06
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Dec 2020 22:17:07
User entered empty.	Mary Bower (b) (4)	19 Dec 2020 22:17:07
	(b) (4)	

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Folder: Illness Visit (3)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:46:24

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:44:27
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 15:34:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Un-verified.	Amy Anderson (b) (4)	15 Jan 2021 17:40:02
User entered '26 Dec 2020' reason for change: Data Entry Error	Amy Anderson (b) (4)	15 Jan 2021 17:40:02
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User entered empty.	Mary Bower (b) (4)	19 Dec 2020 22:17:07

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**Folder: Illness Visit (3)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:17:07

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Folder: Illness Visit (3)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:46:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:20:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:40:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:40:14
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 05:58:07
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	21 Dec 2020 19:00:13
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Dec 2020 22:17:07
User entered empty.	Mary Bower (b) (4)	19 Dec 2020 22:17:07
	(b) (4)	



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Folder: Illness Visit (3)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:46:24

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:46:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Un-verified.	Amy Anderson (b) (4)	15 Jan 2021 17:40:14
User entered '30 Dec 2020' reason for change: Data Entry Error	Amy Anderson (b) (4)	15 Jan 2021 17:40:14
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User entered empty.	Mary Bower (b) (4)	19 Dec 2020 22:17:07

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**Folder: Illness Visit (3)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:17:07

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Folder: Illness Visit (3)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:46:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:36
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:40:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:40:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 05:58:11
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	21 Dec 2020 19:00:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Dec 2020 22:17:07
User entered empty.	Mary Bower (b) (4)	19 Dec 2020 22:17:07
	(b) (4)	

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Folder: Illness Visit (3)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:46:24

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06JAN2021 is recorded under Illness Visit Day 21 in EDC, however the 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) (4), (b) (6)	22 Feb 2021 08:28:35
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06JAN2021 is recorded under Illness Visit Day 21 in EDC, however the 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 'In Preclarus. Resulted as positive. Accession #1F608RC' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 17:11:59
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06JAN2021 is recorded under Illness Visit Day 21 in EDC, however the 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)	01 Feb 2021 04:34:00
DataPoint Un-verified.	Amy Anderson (b) (4)	15 Jan 2021 17:40:26
User entered '06 Jan 2021' reason for change: Data Entry Error	Amy Anderson (b) (4)	15 Jan 2021 17:40:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User entered empty.	Mary Bower (b) (4)	19 Dec 2020 22:17:07

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**Folder: Illness Visit (3)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Mary Bower (b) (4) (b) (4)	19 Dec 2020 22:17:07

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Folder: Illness Visit (3)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:46:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:40:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:40:55
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 05:58:19
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	21 Dec 2020 19:00:24
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Dec 2020 22:17:07
User entered empty.	Mary Bower (b) (4)	19 Dec 2020 22:17:07
	(b) (4)	

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Folder: Illness Visit (3)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:46:24

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 28 in EDC, however the 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)	22 Feb 2021 08:28:41
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 28 in EDC, however the 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 'Not missing. Already resulted. See Preclarus. Accession # 1F608RC.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 17:10:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 28 in EDC, however the 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)	01 Feb 2021 04:34:10
DataPoint Un-verified.	Amy Anderson (b) (4)	15 Jan 2021 17:40:55
User entered '14 Jan 2021' reason for change: Data Entry Error	Amy Anderson (b) (4)	15 Jan 2021 17:40:55
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:20:49
User entered empty.	Mary Bower (b) (4)	19 Dec 2020 22:17:07

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:43:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:36:41



**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:43:25
User entered '13 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 18:36:41

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[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 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:43:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Nov 2020 18:36:41

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'SICKD1'	System	11 Nov 2020 18:36:41

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:44:12

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered '13 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 18:44:12

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered '08:40'	(b) (4), (b) (6)	11 Nov 2020 18:44:12

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered '13 Oct 2020 08:40'	System	11 Nov 2020 18:44:12

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Nov 2020 18:44:12
DataPoint set to visible.	System	11 Nov 2020 18:36:41



US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Nov 2020 18:44:12
DataPoint set to visible.	System	11 Nov 2020 18:36:41

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered '98.4' F	(b) (4), (b) (6)	11 Nov 2020 18:44:12

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Nov 2020 18:44:12

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:44:12

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered '80'	(b) (4), (b) (6)	11 Nov 2020 18:44:12

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'bpm'	System	11 Nov 2020 18:44:12

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered '17'	(b) (4), (b) (6)	11 Nov 2020 18:44:12

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'breaths/min'	System	11 Nov 2020 18:44:12



US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered '115'	(b) (4), (b) (6)	11 Nov 2020 18:44:12

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'mmHg'	System	11 Nov 2020 18:44:12

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:23
User entered '74'	(b) (4), (b) (6)	11 Nov 2020 18:44:12

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'mmHg'	System	11 Nov 2020 18:44:12

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:46:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:44:50

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:46:24**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:44:35
User entered '13 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 18:44:50



US3482094

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:46:24

[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 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:46:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:45:03

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 18:46:23
User entered '13 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 18:45:03

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:10
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:34:20

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:10
User entered '18 Nov 2020'	Hollie Macenczak (b) (4)	18 Nov 2020 21:34:20

US3482094

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[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 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:10
User entered 'Clinic (Clinic)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:34:20

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User entered 'SICKD1'	System	18 Nov 2020 21:34:20

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered '18 Nov 2020'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25



US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered '15:19'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered '18 Nov 2020 15:19'	System	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25
DataPoint set to visible.	System	18 Nov 2020 21:34:20

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25
DataPoint set to visible.	System	18 Nov 2020 21:34:20

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered '98.3' F	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered 'Oral (Oral)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered empty.	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered '61'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25



**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'bpm'	System	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered '16'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'breaths/min'	System	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered '117'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'mmHg'	System	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:59:52
User entered '70'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'mmHg'	System	18 Nov 2020 21:35:25

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55



US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55

US3482094

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:09:47
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:30

US3482094

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:09:47
User entered '18 Nov 2020'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:30

US3482094

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:46:24

[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 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:09:54
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:37

US3482094

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:46:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:09:54
User entered '18 Nov 2020'	Hollie Macenczak (b) (4)	18 Nov 2020 21:35:37

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:11:33
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:40:53

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:11:33
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:40:53

US3482094

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[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 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:11:33
User entered 'Clinic (Clinic)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:40:53



**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User entered 'SICKD1'	System	18 Dec 2020 22:40:53

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:03

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:03

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered '10:36'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:03

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered '17 Dec 2020 10:36'	System	18 Dec 2020 22:44:03

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered missing code ND - Not Done.	Joy Winters (b) (4)	18 Dec 2020 22:44:03
DataPoint set to visible.	(b) (4) System	18 Dec 2020 22:40:53

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered missing code ND - Not Done.	Joy Winters (b) (4)	18 Dec 2020 22:44:03
DataPoint set to visible.	(b) (4) System	18 Dec 2020 22:40:53

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered '98.5' F	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:03



US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered 'Oral (Oral)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:03

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:03

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered '98'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:03

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'bpm'	System	18 Dec 2020 22:44:03

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered '16'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:03

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'breaths/min'	System	18 Dec 2020 22:44:03

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered '122'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:03

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'mmHg'	System	18 Dec 2020 22:44:03



US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:19
User entered '83'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:03

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55
User entered 'mmHg'	System	18 Dec 2020 22:44:03

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55

US3482094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:55

US3482094

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:28
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:04:21

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:46:24**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:28
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:04:21

US3482094

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:46:24

[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 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:34
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:35

**US3482094**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:46:24**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:41
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:12:34
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 22:44:35



**US3482094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:37:37

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '14 Jan 2021'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:37:37

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[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 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Clinic (Clinic)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:37:37

**US3482094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
User entered 'SICKD28'	System	15 Jan 2021 17:37:37

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:23

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '14 Jan 2021'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:23

**US3482094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '9:50'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:23

**US3482094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
User entered '14 Jan 2021 9:50'	System	15 Jan 2021 17:38:23



US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:44
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '98.5' F	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:23

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Oral (Oral)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:23

**US3482094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:23

**US3482094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:50
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '71'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:23

**US3482094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
User entered 'bpm'	System	15 Jan 2021 17:38:23

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:51:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '14'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:23

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
User entered 'breaths/min'	System	15 Jan 2021 17:38:23

**US3482094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '115'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:23



US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
User entered 'mmHg'	System	15 Jan 2021 17:38:23

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:04
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
Signature has been broken indirectly.	(b) (4)	
User signature succeeded.	System	29 Mar 2021 16:06:12
	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
	(b) (4)	
User entered '75'	Amy Anderson (b) (4)	15 Jan 2021 17:38:23
	(b) (4)	

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:46:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
User entered 'mmHg'	System	15 Jan 2021 17:38:23

**US3482094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46

**US3482094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:46:24**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:24
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'No (N)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:31

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:46:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:31

US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:46:24

[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 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Yes (Y)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:38:50



US3482094

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:46:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). Query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'Accession # 1F608RC' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 09:26:31
Query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'Accession # 1F608RC' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 17:08:19
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 10:30:45
User entered '14 Jan 2021'	Amy Anderson (b) (4)	15 Jan 2021 17:38:50

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:04:53

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '21 Jan 2021'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:04:53

US3482094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:46:24

[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 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Clinic (Clinic)'	Lauren Hewitt (b) (4)	21 Jan 2021 17:04:53

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:46:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 17:04:53

US3482094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:46:24

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '21 Jan 2021'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:05:13

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:46:24**

[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 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:11:44
User entered '0'	(b) (4) Amy Anderson (b) (4)	09 Apr 2021 13:44:41
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 13:13:55

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:46:24**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:05:13



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:46:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:11:44
User closed query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 10:15:08
Query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Amy Anderson (b) (4) (b) (4)	09 Apr 2021 13:44:48
User entered 'Amendment 6 or later (Amendment 6 or later)'	Amy Anderson (b) (4) (b) (4)	09 Apr 2021 13:44:41
User opened query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 06:26:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:13:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:46:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '21 Jan 2021'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:05:13

US3482094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:46:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Placebo (Placebo)'	Lauren Hewitt (b) (4)	21 Jan 2021 17:05:13

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:46:24**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Placebo (Placebo)'	Lauren Hewitt (b) (4)	21 Jan 2021 17:05:13

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:46:24**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Placebo (Placebo)'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:05:13

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:46:24**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'No (N)'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:05:13

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:46:24**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User entered '1'	System	21 Jan 2021 17:05:13

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:46:24**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User entered empty.	System	21 Jan 2021 17:05:13



US3482094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:05:57

US3482094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:46:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '21 Jan 2021'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:05:57

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:46:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '11:31'	Lauren Hewitt (b) (4)	21 Jan 2021 17:05:57

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:46:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User entered '21 Jan 2021 11:31'	System	21 Jan 2021 17:05:57

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:46:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:06:09

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:46:24**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '21 Jan 2021'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:06:09

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:46:24**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:04:39
User entered '11:26'	(b) (4) Lauren Hewitt (b) (4)	21 Jan 2021 17:06:09

**US3482094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:46:24**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:10
User entered '21 Jan 2021 11:26'	System	21 Jan 2021 17:06:09



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:46:24**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:38
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:50:12

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:46:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User closed query 'Per MM: Please update AE to provide symptoms.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 11:12:59
Query 'Per MM: Please update AE to provide symptoms.' answered with 'SYMPTOMS RECORDED IN SYMPTOM LOG OF ILLNESS AND CONVALESCENT VISITS.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:53:49
User opened query 'Per MM: Please update AE to provide symptoms.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:36:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:31:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:31:37
Data point term sent to Coder	System	11 Nov 2020 22:30:53
User entered 'UPPER RESPIRATORY INFECTION'	(b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

US3482094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:46:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:36
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

US3482094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
User entered empty.	System	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:42
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:44
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:45
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
User entered empty.	System	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

US3482094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:46:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:11:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:00
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:01
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

US3482094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:46:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:03
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

US3482094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:46:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:07
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

US3482094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:46:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:14
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:17
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:46:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:18
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:24
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

US3482094

Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:26
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:31
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'COUGH, RUNNY NOSE, NASAL CONGESTION, SORE THROAT SYMPTOMS.'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
User entered '0'	System	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24
User entered 'I'	System	11 Nov 2020 22:30:46

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:24

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Nov 2020 22:49:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 22:49:37
Data point term sent to Coder	System	11 Nov 2020 22:48:21
User entered 'HEADACHE'	(b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:52
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:55
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:12:57
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:46:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
User entered empty.	System	11 Nov 2020 22:47:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
User closed query 'Source document is not marked with a reply. Please verify and update source or EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:38:08
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:38:07
Query 'Source document is not marked with a reply. Please verify and update source or EDC as needed.' answered with 'updated' (Site from CRA).	Michele McCullough (b) (4)	26 Apr 2021 15:33:46
User opened query 'Source document is not marked with a reply. Please verify and update source or EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:21:03
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 15:20:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:17:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:07
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
User entered empty.	System	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:14
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:16
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:18
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:46:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:24
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:26
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:33
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:35
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:46:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:38
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:43
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:44
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:53
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:57
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:21:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
User entered '0'	System	11 Nov 2020 22:47:50

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31
User entered 'I'	System	11 Nov 2020 22:47:50



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:31

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45

US3482094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:46:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:07
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 22:49:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:49:38
Data point term sent to Coder	System	11 Nov 2020 22:49:24
User entered 'JOINT ACHES, GENERALIZED'	(b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

US3482094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:14
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:18
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:46:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
User entered empty.	System	11 Nov 2020 22:49:04

US3482094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	12 Nov 2020 17:50:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 17:50:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 17:50:41
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 22:49:04
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 22:49:04

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
User entered empty.	System	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:22:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:00
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:46:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

US3482094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:46:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:46:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:33
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:35
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:24:41
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:38:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:38:33
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:38:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:38:36
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:07
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:49:04

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:46:24

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
User entered '0'	System	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45
User entered 'I'	System	11 Nov 2020 22:49:04

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:45

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43

US3482094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:46:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Nov 2020 22:50:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 22:50:37
Data point term sent to Coder	System	11 Nov 2020 22:50:24
User entered 'MYALGIAS, GENERALIZED'	(b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:35
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
User entered empty.	System	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:37
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
User entered empty.	System	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

US3482094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:46:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:52
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:39:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:01
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:46:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:03
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:07
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:10
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:46:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:12
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:46:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:14
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:16
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:18
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:21
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:46:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:23
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:46:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:25
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:50:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:46:24

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
User entered '0'	System	11 Nov 2020 22:50:15

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43
User entered 'I'	System	11 Nov 2020 22:50:15



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:43

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:46:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 22:53:36
Data point term sent to Coder	(b) (4)	11 Nov 2020 22:53:36
User entered 'FATIGUE'	System	11 Nov 2020 22:52:25
	(b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:43
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:45
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:50
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:52
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
User entered empty.	System	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:54
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '18 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:40:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
User entered empty.	System	11 Nov 2020 22:51:25

US3482094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:46:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:00
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

US3482094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:46:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:04
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:08
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:46:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

US3482094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:46:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:11
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:15
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:17
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:20
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25



**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:22
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:41:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:42:19
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:42:26
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:42:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:42:29
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:42:31
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:42:33
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:47:26
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:47:28
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
User entered '0'	System	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40
User entered 'I'	System	11 Nov 2020 22:51:25

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:40

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:32:09
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:26:50
User entered		
'USA-US106-2020-mRNA-1273-P301000011'	System	23 Dec 2020 14:26:41
User entered 'New'	(b) (4), (b) (6)	23 Dec 2020 14:26:41

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:49
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)	21 Dec 2020 21:33:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Dec 2020 21:33:36
Data point term sent to Coder	System	21 Dec 2020 18:20:51
Coding entries removed.	Amy Anderson (b) (4)	21 Dec 2020 18:20:21
	(b) (4)	
User entered 'covid-19' reason for change: New Information	Amy Anderson (b) (4)	21 Dec 2020 18:20:21
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Influenza like illness, LLT: Flu-like illness - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 23:56:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 23:56:44
	(b) (4)	
Data point term sent to Coder	System	18 Dec 2020 23:55:34
User entered 'Flu-like illness'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:51
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:54:54



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:53
User entered 'No (N)'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:55
User closed query 'Per CDM: Response to 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is NO, however Covid-19 Diagnostic Test for Covid-19 Assessment on 17Dec2020 has 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR?' recorded as YES. Please review and update as appropriate or clarify data.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 04:31:49
Query 'Per CDM: Response to 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is NO, however Covid-19 Diagnostic Test for Covid-19 Assessment on 17Dec2020 has 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR?' recorded as YES. Please review and update as appropriate or clarify data.' answered with 'updated' (Site from DM).	Michele McCullough	22 Dec 2020 14:55:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Response to 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is NO, however Covid-19 Diagnostic Test for Covid-19 Assessment on 17Dec2020 has 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR?' recorded as YES. Please review and update as appropriate or clarify data.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 10:42:11
User entered 'No (N)'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:30:02
User entered '09 Dec 2020'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:30:35
User entered empty.	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 23:54:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:55:05
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 00:07:58
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	15 Jan 2021 00:07:58
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:30:37
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:54:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:54:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:38:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 00:08:10
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 00:07:58
User entered '5 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	15 Jan 2021 00:07:58
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)	30 Dec 2020 18:45:15
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:30:53
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:54:54

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:06
User entered empty.	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 23:54:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:54:59
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:37:05
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:31:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:54:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:55:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	28 Jan 2021 15:49:38
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	28 Jan 2021 15:26:32
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4)	28 Jan 2021 15:26:32
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:37:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:31:11
User entered 'No (N)'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:13
User entered '0'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:17
User entered '0'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:19
User entered '0'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:21
User entered empty.	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:22
User entered empty.	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:24
User entered empty.	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:49
User entered empty.	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:51
User entered '0'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

**US3482094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:52
User entered '0'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:55:08
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User entered '0' reason for change: Per Query Resolution	(b) (4)	
	Amy Anderson (b) (4)	28 Jan 2021 15:49:38
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:37:05
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:31:48
User entered '0'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:31:46
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:54:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:45
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:43
User entered 'Not Applicable (NOT APPLICABLE)'	Amy Anderson (b) (4)	21 Dec 2020 18:20:21
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:41
User entered '0'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:31:39
User entered 'I'	Joy Winters (b) (4)	18 Dec 2020 23:54:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:55:13
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:53:08
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Diagnostic chest Xray indicated in con procedures' (Site from DM).	Mari Hart (b) (4) (b) (4)	25 Mar 2021 14:40:14
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:19:39
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	13 Mar 2021 03:15:06
DataPoint Un-verified.	Amy Anderson (b) (4) (b) (4)	05 Mar 2021 20:26:46
User entered '1' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	05 Mar 2021 20:26:46
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:31:37
User entered '0'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:54:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:55:17
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:38:29
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'UPDATED.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 00:08:24
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 00:07:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	15 Jan 2021 00:07:58
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 18:44:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:31:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:54:54

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:31:35
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:54:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:55:24
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:15:06
User closed query 'PV Query: Please note that events of COVID-19 are collected as a standard per protocol; therefore, this event should not be reported as an SAE based on the seriousness criterion of "Other medically important event". Please reassess whether this event meets the standard definitions for an SAE and update accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:05:36
Query 'PV Query: Please note that events of COVID-19 are collected as a standard per protocol; therefore, this event should not be reported as an SAE based on the seriousness criterion of "Other medically important event". Please reassess whether this event meets the standard definitions for an SAE and update accordingly.' answered with 'Confirmed. Event was not an SAE. Patient was not hospitalized and he has recovered.' (Site from Safety).	Amy Anderson (b) (4) (b) (4)	28 Jan 2021 15:26:20
User opened query 'PV Query: Please note that events of COVID-19 are collected as a standard per protocol; therefore, this event should not be reported as an SAE based on the seriousness criterion of "Other medically important event". Please reassess whether this event meets the standard definitions for an SAE and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 21:39:58
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Jan 2021 19:44:39
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Jan 2021 19:44:39
DataPoint Un-verified.	(b) (4), (b) (6)	22 Jan 2021 19:44:39
User entered 'SYMPTOMATIC COVID-19, MEETING SEVERE CLASSIFICATION BECAUSE PULSE OX WENT TO 93%. WAS TREATED WITH A NUMBER OF MEDS, AS REPORTED, AND ULTIMATELY RESOLVED.' reason for change: Per Query Resolution	(b) (4), (b) (6)	22 Jan 2021 19:44:39

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:46:24

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Jan 2021 18:37:05
User closed query 'PV Query: It was reported in the case narrative that the subject had an ER visit. Please confirm that the subject was not admitted or hospitalized overnight.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 18:38:31
Query 'PV Query: It was reported in the case narrative that the subject had an ER visit. Please confirm that the subject was not admitted or hospitalized overnight.' answered with 'patient was never admitted to the hospital.' (Site from Safety).	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:43:37
User opened query 'PV Query: It was reported in the case narrative that the subject had an ER visit. Please confirm that the subject was not admitted or hospitalized overnight.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 18:44:55
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:32:04
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:54:54

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Jan 2021 15:26:32
User entered '1'	System	21 Jan 2021 18:37:05
User entered '0'	System	18 Dec 2020 23:54:54



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Dec 2020 23:54:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:46:24

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:51:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Tiffany Lee (b) (4)	13 Oct 2020 16:15:56
User entered 'No (N)'	(b) (4)	
	Geoffrey Kamau (b) (4)	20 Aug 2020 17:35:30
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: DEXCHLORPHENIRAMINE MALEATE;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: RYMED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 17:53:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 17:53:39
Data point term sent to Coder	System	12 Nov 2020 17:52:41
Coding entries removed.	(b) (4), (b) (6)	12 Nov 2020 17:52:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: DEXCHLORPHENIRAMINE MALEATE;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: RYMED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:21:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:21:21
Data point term sent to Coder	System	13 Oct 2020 16:20:12
User entered 'Rymed'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:13
User entered 'No (N)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:14
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 10:37:34
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 10:36:15
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'AE INPUT in eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:53:18
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'MEDICATION INDICATION UPDATED' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:53:04
User entered 'UPPER RESPIRATORY (URI) SYMPTOMS' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Nov 2020 17:52:40
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:39:06
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:38:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
User entered 'Treatment for allergy and cold symptoms'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:17
User entered '2/10'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:18
User entered 'mg (mg)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:20
User entered empty.	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:21
User entered 'twice daily (BID)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:26
User entered empty.	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:27
User entered 'Oral (ORAL)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:29
User entered empty.	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:31
User entered '12 Oct 2020'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:33
User entered '0'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:35
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 17:52:40
User entered 'Yes (Y)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:46:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:37
User entered '14 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 17:52:40
User entered empty.	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:19:40
User entered 'No (N)'	Tiffany Lee (b) (4) (b) (4)	13 Oct 2020 16:19:56

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User entered '2'	System	13 Oct 2020 16:19:56

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User entered '1'	System	13 Oct 2020 16:19:56

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:20
User entered '804 (804)'	System	13 Oct 2020 16:19:56

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 23:54:11
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 23:54:11
Data point term sent to Coder Coding entries removed.	System Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:48:28 18 Dec 2020 23:48:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 23:42:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 23:42:53
Data point term sent to Coder	System	18 Dec 2020 23:41:25
User entered 'Centrum Multivitamin'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User closed query 'Per DM CLR: The indication signifies prophylaxis (Health Promotion). However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 07:48:21
Query 'Per DM CLR: The indication signifies prophylaxis (Health Promotion). However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' answered with 'changed' (Site from DM).	Amy Anderson (b) (4) (b) (4)	09 Feb 2021 12:34:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	09 Feb 2021 12:34:37
User opened query 'Per DM CLR: The indication signifies prophylaxis (Health Promotion). However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 20:50:37
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'HEALTH PROMOTION' reason for change: Data Entry Error	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:48:17
User entered 'Health promotioon'	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:40:43
	(b) (4)	



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '2'	Joy Winters (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'tablet (TABLET)'	Joy Winters (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	Joy Winters (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'once daily (QD)'	Joy Winters (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	Joy Winters (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:25
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Oral (ORAL)'	Joy Winters (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	Joy Winters (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '16 Dec 2020'	Joy Winters (b) (4)	18 Dec 2020 23:40:43



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '0'	Joy Winters (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:09
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Yes (Y)'	Joy Winters (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:14
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	Joy Winters (b) (4)	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 23:42:19
User entered 'No (N)' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:42:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Dec 2020 23:40:43
	Joy Winters (b) (4)	18 Dec 2020 23:40:43
	(b) (4)	

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 23:40:43

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 23:40:43

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Dec 2020 23:40:43

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:46:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM; MANGANESE;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC, PRODUCTSYNONYM: AIRBORNE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:12
Data point term sent to Coder	System	21 Dec 2020 13:24:12
Coding entries removed.	Amy Anderson (b) (4)	21 Dec 2020 13:23:29
User entered 'AIRBORNE supplement (Vitamins C & E, Echinacea & Ginger)' reason for change: Data Entry Error	Amy Anderson (b) (4)	21 Dec 2020 13:23:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM; MANGANESE;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC, PRODUCTSYNONYM: AIRBORNE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 23:54:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 23:54:11



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM; MANGANESE;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC, PRODUCTSYNONYM: AIRBORNE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 23:52:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 23:52:38
Data point term sent to Coder	System	18 Dec 2020 23:52:32
Query 'For coding purposes, Please enter the active ingredient(s) in parenthesis after drug name, or specify if unknown, and please make your changes to the reported term.' canceled (Site from System).	Coder Import (b) (4)	18 Dec 2020 23:51:53
Data point term sent to Coder	System	18 Dec 2020 23:50:29
User entered 'AIRBORNE' reason for change: Data Entry Error	Joy Winters (b) (4)	18 Dec 2020 23:49:41
User opened query 'For coding purposes, Please enter the active ingredient(s) in parenthesis after drug name, or specify if unknown, and please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	18 Dec 2020 23:45:49
Data point term sent to Coder	System	18 Dec 2020 23:44:27
User entered 'Airborne Supplement'	Joy Winters (b) (4)	18 Dec 2020 23:44:19

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:52
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User closed query 'Per DM CLR: The indication signifies prophylaxis (Health Promotion). However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:16:25
Query 'Per DM CLR: The indication signifies prophylaxis (Health Promotion). However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' answered with 'updated' (Site from DM).	Amy Anderson (b) (4) (b) (4)	09 Feb 2021 12:35:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	09 Feb 2021 12:35:07
User opened query 'Per DM CLR: The indication signifies prophylaxis (Health Promotion). However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 20:51:01
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:44:19

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Health Promotion'	Joy Winters (b) (4)	18 Dec 2020 23:44:19

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '2'	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:44:19

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:59
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'tablet (TABLET)'	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:44:19

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:46:24**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:44:19
	(b) (4)	

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'once daily (QD)'	Joy Winters (b) (4)	18 Dec 2020 23:44:19

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:44:19
	(b) (4)	



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Oral (ORAL)'	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:44:19

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:46:24**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	(b) (4)	
	Joy Winters (b) (4)	18 Dec 2020 23:44:19
	(b) (4)	

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:20
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '16 Dec 2020'	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:44:19

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '0'	Joy Winters (b) (4)	18 Dec 2020 23:44:19

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:23:58
User closed query 'Source document has end date entered as 30Dec20. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:23:21
Query 'Source document has end date entered as 30Dec20. Please verify and update.' answered with 'updated' (Site from CRA).	Amy Anderson (b) (4)	19 Apr 2021 14:25:44
Signature has been broken.	Amy Anderson (b) (4)	19 Apr 2021 14:25:05
User entered 'No (N)' reason for change: New Information	Amy Anderson (b) (4)	19 Apr 2021 14:25:05
User opened query 'Source document has end date entered as 30Dec20. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:04:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Yes (Y)'	Joy Winters (b) (4)	18 Dec 2020 23:44:19

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:23:58
Signature has been broken.	Amy Anderson (b) (4)	19 Apr 2021 14:25:05
User entered '30 Dec 2020' reason for change: New Information	(b) (4) Amy Anderson (b) (4)	19 Apr 2021 14:25:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	(b) (4) Joy Winters (b) (4)	18 Dec 2020 23:44:19
	(b) (4)	

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'No (N)'	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:44:19

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
User entered '1'	System	18 Dec 2020 23:44:19



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
User entered '1'	System	18 Dec 2020 23:44:19

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:40
User entered '804 (804)'	System	18 Dec 2020 23:44:19

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
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)	09 Feb 2021 12:36:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 12:36:45
Data point term sent to Coder	System	09 Feb 2021 12:36:17
Coding entries removed.	Amy Anderson (b) (4)	09 Feb 2021 12:35:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:22:35
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)	18 Dec 2020 23:47:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 23:47:48
Data point term sent to Coder	System	18 Dec 2020 23:46:28
User entered 'Acetaminophen'	Joy Winters (b) (4)	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:37
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:04:22
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User closed query 'Per DM CLR: Please review indication if this refers to AE#6 COVID-19. If so, please reconcile event terms so there is an appropriate match. Else, note that this condition is not recorded on AE eCRF. Update applicable ecrfs as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:02:54
Query 'Per DM CLR: Please review indication if this refers to AE#6 COVID-19. If so, please reconcile event terms so there is an appropriate match. Else, note that this condition is not recorded on AE eCRF. Update applicable ecrfs as appropriate. Otherwise, provide clarification. ' answered with 'added covid-19' (Site from DM).	Amy Anderson (b) (4) (b) (4)	09 Feb 2021 12:35:53
DataPoint Un-verified.	Amy Anderson (b) (4) (b) (4)	09 Feb 2021 12:35:40
User entered 'BODY ACHES (COVID-19)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	09 Feb 2021 12:35:40
User opened query 'Per DM CLR: Please review indication if this refers to AE#6 COVID-19. If so, please reconcile event terms so there is an appropriate match. Else, note that this condition is not recorded on AE eCRF. Update applicable ecrfs as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 20:52:22
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:22:39
User entered 'Body aches'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:40
User entered '1000'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:42
User entered 'mg (mg)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:43
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:44
User entered 'as needed (PRN)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:46
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:47
User entered 'Oral (ORAL)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:49
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:50
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:52
User entered '0'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:54
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 23:46:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 23:46:32
User entered 'No (N)' reason for change: Data Entry Error	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:32
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 23:46:18
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:55
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:22:57
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:46:18

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User entered empty.	System	18 Dec 2020 23:46:18

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User entered empty.	System	18 Dec 2020 23:46:18

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:21
User entered empty.	System	18 Dec 2020 23:46:18

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:23:28
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: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:39
Data point term sent to Coder	System	21 Dec 2020 18:54:24
User entered 'Methylprednisolone' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:53:52
Data point term sent to Coder	System	21 Dec 2020 18:21:52
Coding entries removed.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:21:09
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: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 23:54:11
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 23:54:11
Data point term sent to Coder	System	18 Dec 2020 23:52:32
User entered 'Methylprednisone'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:23:30
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:23:50
User entered 'covid-19' reason for change: New Information	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:21:09
User entered 'Flu-like illness'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:23:53
User entered '12' reason for change: Data Entry Error	Amy Anderson (b) (4)	21 Dec 2020 18:50:49
User entered '24'	(b) (4) Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:23:54
User entered 'mg (mg)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:01
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:23:59
User entered 'twice daily (BID)' reason for change:	Amy Anderson (b) (4)	21 Dec 2020 18:50:49
Data Entry Error	(b) (4)	
User entered 'once (ONCE)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:06
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:08
User entered 'Oral (ORAL)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:10
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:12
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:14
User entered '0'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:15
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:17
User entered '17 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:19
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:52:05

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User entered '2'	System	21 Dec 2020 18:50:49
User entered empty.	System	18 Dec 2020 23:52:05

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User entered '1'	System	21 Dec 2020 18:50:49
User entered empty.	System	18 Dec 2020 23:52:05

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:57
User entered '804 (804)'	System	21 Dec 2020 18:50:49
User entered empty.	System	18 Dec 2020 23:52:05

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:32
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: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:39
Data point term sent to Coder	System	21 Dec 2020 18:54:24
User entered 'Methylprednisolone' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:02
Data point term sent to Coder	System	21 Dec 2020 18:21:52
Coding entries removed.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:21:26
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: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 23:54:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 23:54:41
Data point term sent to Coder	System	18 Dec 2020 23:53:33
User entered 'Methylprednisone'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:34
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:36
User entered 'covid-19' reason for change: New Information	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:21:26
User entered 'Flu-like illness'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:38
User entered '10' reason for change: Data Entry Error	Amy Anderson (b) (4)	21 Dec 2020 18:51:08
User entered '20'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:40
User entered 'mg (mg)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:41
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:43
User entered 'twice daily (BID)' reason for change:	Amy Anderson (b) (4)	21 Dec 2020 18:51:08
Data Entry Error	(b) (4)	
User entered 'once (ONCE)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:44
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:46
User entered 'Oral (ORAL)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:47
User entered empty.	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:24:49
User entered '18 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:28:28
User entered '0'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:28:31
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:46:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:28:32
User entered '18 Dec 2020'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:28:34
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User entered '2'	System	21 Dec 2020 18:51:08
User entered empty.	System	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User entered '1'	System	21 Dec 2020 18:51:08
User entered empty.	System	18 Dec 2020 23:53:28

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:46:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:07
User entered '804 (804)'	System	21 Dec 2020 18:51:08
User entered empty.	System	18 Dec 2020 23:53:28



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:38
Data point term sent to Coder	System	21 Dec 2020 18:21:54
Data point term sent to Coder	System	21 Dec 2020 13:26:17
User entered 'cetirizine'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:23
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:25
User entered 'covid-19' reason for change: New Information	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:21:43
User entered 'flu-like illness'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:27
User entered '10'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:40
User entered 'mg (mg)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:44
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:43
User entered 'once daily (QD)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:46
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:48
User entered 'Oral (ORAL)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:50
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:51
User entered '18 Dec 2020'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:54
User entered '0'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:34:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Jan 2021 17:34:52
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:29:56
User entered 'Yes (Y)'	Amy Anderson (b) (4)	21 Dec 2020 13:25:40
	(b) (4)	

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:34:52
User entered '07 Jan 2021' reason for change: Data Entry Error	(b) (4)	15 Jan 2021 17:34:52
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:29:57
User entered empty.	Amy Anderson (b) (4)	21 Dec 2020 13:25:40
	(b) (4)	

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:29:59
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:25:40

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User entered '1'	System	21 Dec 2020 13:25:40



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User entered '1'	System	21 Dec 2020 13:25:40

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:18
User entered '804 (804)'	System	21 Dec 2020 13:25:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:35:50
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)	21 Dec 2020 21:33:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:37
Data point term sent to Coder	System	21 Dec 2020 18:22:55
Data point term sent to Coder	System	21 Dec 2020 13:27:18
User entered 'aspirin'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:35:57
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:35:58
User entered 'covid-19' reason for change: New Information	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:22:00
User entered 'flu-like illness'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:06:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:33:57
User entered '162' reason for change: Data Entry Error	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:33:57
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:36:00
User entered '324'	Amy Anderson (b) (4)	21 Dec 2020 13:26:32
	(b) (4)	

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:02
User entered 'mg (mg)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:06
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:07
User entered 'once daily (QD)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:09
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:10
User entered 'Oral (ORAL)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:12
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:13
User entered '17 Dec 2020'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:15
User entered '0'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
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) (4), (b) (6)	12 Mar 2021 07:53:29
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 'updated' (Site from DM).	Sarah Bechnak (b) (4) (b) (4)	11 Mar 2021 19:04:15
DataPoint Un-verified.	Sarah Bechnak (b) (4) (b) (4)	11 Mar 2021 19:04:05
User entered 'No (N)' reason for change: Data Entry Error	Sarah Bechnak (b) (4) (b) (4)	11 Mar 2021 19:04:05
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)	30 Jan 2021 20:53:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:36:17
User entered 'Yes (Y)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	(b) (4)	
	Sarah Bechnak (b) (4)	11 Mar 2021 19:04:05
User entered '11 Feb 2021' reason for change: Data Entry Error	(b) (4)	11 Mar 2021 19:04:05
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:36:18
User entered empty.	Amy Anderson (b) (4)	21 Dec 2020 13:26:32
	(b) (4)	



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:20
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 13:26:32

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User entered '1'	System	21 Dec 2020 13:26:32

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User entered '1'	System	21 Dec 2020 13:26:32

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:29:26
User entered '804 (804)'	System	21 Dec 2020 13:26:32

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:38
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: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:55
Data point term sent to Coder	System	21 Dec 2020 18:53:22
User entered 'methylprednisolone'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:40
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:41
User entered 'covid-19'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:46:24**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:43
User entered '8'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:46
User entered 'mg (mg)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:48
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:49
User entered 'twice daily (BID)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:51
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:46:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:52
User entered 'Oral (ORAL)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:54
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:56
User entered '19 Dec 2020'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:58
User entered '0'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:46:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:36:59
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:37:00
User entered '19 Dec 2020'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:37:02
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:52:25

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User entered '2'	System	21 Dec 2020 18:52:25

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User entered '1'	System	21 Dec 2020 18:52:25

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:34
User entered '804 (804)'	System	21 Dec 2020 18:52:25

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:42:35
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: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:39
Data point term sent to Coder	System	21 Dec 2020 18:55:26
User entered 'Methylprednisolone'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:42:37
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 18:55:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 18:55:03
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:55:03
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 18:54:57
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:42:38
User entered 'covid-19'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:42:42
User entered '6'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:42:44
User entered 'mg (mg)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:42:45
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:44:23
User entered 'twice daily (BID)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:44:25
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:44:40
User entered 'Oral (ORAL)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:44:43
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:44:58
User entered '20 Dec 2020'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:00
User entered '0'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:46:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:02
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:46:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:04
User entered '20 Dec 2020'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:06
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:54:57

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User entered '2'	System	21 Dec 2020 18:54:57

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:46:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User entered '1'	System	21 Dec 2020 18:54:57

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:38
User entered '804 (804)'	System	21 Dec 2020 18:54:57



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:35
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: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:39
Data point term sent to Coder	System	21 Dec 2020 18:57:27
User entered 'Methylprednisolone'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:37
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:38
User entered 'covid-19'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:40
User entered '4'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:41
User entered 'mg (mg)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:45
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:47
User entered 'twice daily (BID)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:49
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:50
User entered 'Oral (ORAL)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:51
User entered empty.	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:53
User entered '21 Dec 2020'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:45:55
User entered '0'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:46:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:46:15
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:46:18
User entered '21 Dec 2020'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:46:20
User entered 'No (N)'	Amy Anderson (b) (4) (b) (4)	21 Dec 2020 18:57:13

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User entered '2'	System	21 Dec 2020 18:57:13



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:46:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User entered '1'	System	21 Dec 2020 18:57:13

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:30:46
User entered '804 (804)'	System	21 Dec 2020 18:57:13

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:47:14
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)	23 Dec 2020 17:22:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 17:22:51
Data point term sent to Coder	System	23 Dec 2020 17:21:38
User entered 'Acetaminophen'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:47:15
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:47:17
User entered 'Fever related to COVID19'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:47:18
User entered '1000'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:47:20
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:47:00
User entered empty.	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:46:59
User entered 'as needed (PRN)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:46:57
User entered empty.	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:46:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:46:56
User entered 'Oral (ORAL)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:46:54
User entered empty.	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:46:52
User entered '22 Dec 2020'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:46:51
User entered '0'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:36:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Jan 2021 17:36:49
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:46:50
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	23 Dec 2020 17:20:48
	(b) (4)	

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:36:49
User entered '03 Jan 2021' reason for change: New Information	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:36:49
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:46:48
User entered empty.	Michelle Wiles (b) (4)	23 Dec 2020 17:20:48
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:46:47
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:20:48

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User entered empty.	System	23 Dec 2020 17:20:48

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User entered empty.	System	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:46:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:37
User entered empty.	System	23 Dec 2020 17:20:48

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:00
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, PRODUCTSYNONYM: DEXMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 17:24:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 17:24:45
Data point term sent to Coder	System	23 Dec 2020 17:21:38
User entered 'Dexamethasone'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:03
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:05
User entered 'COVID19'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:07
User entered '4'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:09
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:11
User entered empty.	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:12
User entered 'twice daily (BID)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:14
User entered empty.	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:46:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:15
User entered 'Oral (ORAL)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:17
User entered empty.	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:19
User entered '22 Dec 2020'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:48:53
User entered '0'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:48:51
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:36:22
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:48:49
User entered '27 Dec 2020' reason for change: New Information	Amy Anderson (b) (4) (b) (4)	27 Dec 2020 18:36:22
User entered empty.	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:47:35
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	23 Dec 2020 17:21:30

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User entered '2'	System	23 Dec 2020 17:21:30

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User entered '1'	System	23 Dec 2020 17:21:30

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:15:17
User entered '804 (804)'	System	23 Dec 2020 17:21:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:46
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)	25 Dec 2020 09:40:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:40:19
Data point term sent to Coder	System	24 Dec 2020 16:02:07
User entered 'Albuterol Nebulizer'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:47
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:46:24**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:48
User entered 'COVID 19'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:50
User entered '2.5'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:51
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:56
User entered empty.	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:57
User entered 'as needed (PRN)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:49:59
User entered empty.	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:46:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:50:01
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:50:02
User entered empty.	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:50:04
User entered '23 Dec 2020'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:50:06
User entered '0'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:35:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Jan 2021 17:35:39
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:51:09
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	24 Dec 2020 16:01:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:35:39
User entered '05 Jan 2021' reason for change: Data Entry Error	(b) (4)	15 Jan 2021 17:35:39
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:51:12
User entered empty.	Michelle Wiles (b) (4)	24 Dec 2020 16:01:53
	(b) (4)	

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:51:32
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	24 Dec 2020 16:01:53

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User entered empty.	System	24 Dec 2020 16:01:53

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:46:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User entered empty.	System	24 Dec 2020 16:01:53

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:28:47
User entered empty.	System	24 Dec 2020 16:01:53



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:52:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Dec 2020 21:34:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Dec 2020 21:34:29
Data point term sent to Coder	System	26 Dec 2020 20:32:15
Data point term sent to Coder	System	26 Dec 2020 20:27:09
User entered 'azithromycin'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:52:11
User entered 'No (N)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:52:14
User entered 'treatment for possible secondary infection due to continued high fever' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	26 Dec 2020 20:31:51
User entered 'fever'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:52:18
User entered '500'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:52:20
User entered 'mg (mg)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:52:23
User entered empty.	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:52:26
User entered 'once (ONCE)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:52:29
User entered empty.	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:52:57
User entered 'Oral (ORAL)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:19
User entered empty.	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:01
User entered '20 Dec 2020'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:02
User entered '0'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:09
User entered 'No (N)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:05
User entered '20 Dec 2020'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:08
User entered 'No (N)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:26:30

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User entered empty.	System	26 Dec 2020 20:26:30



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User entered empty.	System	26 Dec 2020 20:26:30

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:36:45
User entered empty.	System	26 Dec 2020 20:26:30

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Dec 2020 21:34:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Dec 2020 21:34:29
Data point term sent to Coder	System	26 Dec 2020 20:32:17
Data point term sent to Coder	System	26 Dec 2020 20:28:10
User entered 'azithromycin'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:43
User entered 'No (N)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:45
User entered 'treatment for possible secondary infection due to continued high fever' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	26 Dec 2020 20:32:06
User entered 'fever'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:47
User entered '250'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:50
User entered 'mg (mg)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:53
User entered empty.	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:55
User entered 'once daily (QD)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:53:58
User entered empty.	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:54:20
User entered 'Oral (ORAL)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:54:22
User entered empty.	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:54:27
User entered '21 Dec 2020'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:54:30
User entered '0'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:54:33
User entered 'No (N)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:54:35
User entered '24 Dec 2020'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:54:36
User entered 'No (N)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:27:24

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User entered '1'	System	26 Dec 2020 20:27:24

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User entered '1'	System	26 Dec 2020 20:27:24

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:37:13
User entered '804 (804)'	System	26 Dec 2020 20:27:24

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Dec 2020 21:31:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Dec 2020 21:31:25
Data point term sent to Coder	System	26 Dec 2020 20:33:17
Data point term sent to Coder	System	26 Dec 2020 20:29:12
User entered 'doxycycline'	Hollie Macenczak (b) (4) (b) (4) (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:04
User entered 'No (N)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:11
User entered 'treatment for possible secondary infection due to continued high fever' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	26 Dec 2020 20:32:20
User entered 'fever'	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:10
User entered '100'	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:13
User entered 'mg (mg)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:15
User entered empty.	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:34
User entered 'twice daily (BID)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:36
User entered empty.	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:38
User entered 'Oral (ORAL)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:40
User entered empty.	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:43
User entered '24 Dec 2020'	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:45
User entered '0'	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User closed query 'This has not been updated. Please update.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 15:36:59
Query 'This has not been updated. Please update.' answered with 'updated to no in source' (Site from CRA).	Amy Anderson (b) (4) (b) (4)	21 Apr 2021 16:54:37
User opened query 'This has not been updated. Please update.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:26:30
User closed query 'Source document says this is ongoing please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:26:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
Query 'Source document says this is ongoing please verify and update as needed.' answered with 'updated' (Site from CRA).	Amy Anderson (b) (4) (b) (4)	19 Apr 2021 14:28:11
User opened query 'Source document says this is ongoing please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:09:27
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:36:10
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:36:10
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:55:54
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)  (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:23:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:36:10
User entered '03 Jan 2021' reason for change: New Information	(b) (4)	
	Amy Anderson (b) (4)	15 Jan 2021 17:36:10
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:55:56
User entered empty.	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 17:55:58
User entered 'No (N)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:28:40

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User entered '2'	System	26 Dec 2020 20:28:40

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User entered '1'	System	26 Dec 2020 20:28:40

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:49
User entered '804 (804)'	System	26 Dec 2020 20:28:40

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:46:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
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: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Jan 2021 17:33:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 17:33:54
Data point term sent to Coder	System	15 Jan 2021 17:33:10
User entered 'METHYLPREDNISOLONE'	Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:46:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:19
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	15 Jan 2021 17:32:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 17:32:46
User entered 'No (N)' reason for change: Data Entry Error	Amy Anderson (b) (4)	15 Jan 2021 17:32:46
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 17:32:39
User entered empty.	Amy Anderson (b) (4)	15 Jan 2021 17:32:39
	(b) (4)	



US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'covid-19'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '2'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:46:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:27
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'mg (mg)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:30
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:46:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:49
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'twice daily (BID)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:46:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:51
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:55
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'Oral (ORAL)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:10:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39



**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:00
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '22 Dec 2020'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '0'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:04
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'No (N)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '22 Dec 2020'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

US3482094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:46:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'No (N)'	(b) (4) Amy Anderson (b) (4) (b) (4)	15 Jan 2021 17:32:39

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
User entered '2'	System	15 Jan 2021 17:32:39

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
User entered '1'	System	15 Jan 2021 17:32:39

**US3482094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:46:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:31:10
User entered '804 (804)'	System	15 Jan 2021 17:32:39



US3482094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:46:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:43:52
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 17:16:52
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 17:16:41
User entered 'Yes (Y)' reason for change: New Information	Hollie Macenczak (b) (4)	26 Dec 2020 20:23:14
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 16:48:34

US3482094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:46:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '24 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	26 Dec 2020 20:23:40

US3482094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:46:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered 'chest xray'	(b) (4) Hollie Macenczak (b) (4)	26 Dec 2020 20:23:40

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:46:24

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User closed query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#6 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 13:01:58
Query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#6 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' answered with 'I have updated the AE to indicate con procedure.' (Site from DM).	Amy Anderson (b) (4) (b) (4)	05 Mar 2021 20:27:59
User opened query 'Per DM CLR: Indication = Adverse Event. However the corresponding AE#6 "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:09:16
User entered 'Adverse Event (AE)'	Hollie Macenczak (b) (4)	26 Dec 2020 20:23:40

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:46:24

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:11:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	26 Dec 2020 20:23:40

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'USA-US106-2020-MRNA-1273-P301000011'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41



**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

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Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

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Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Easton'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Easton'	System	23 Dec 2020 14:26:41

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Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Beshears'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change:	(b) (4), (b) (6)	21 Jan 2021 18:36:08
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Beshears'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08



**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:37
User entered 'US'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 19:41:15
User entered '5'	System	29 Jan 2021 16:09:40
User entered '4'	System	25 Jan 2021 15:15:58
User entered '3'	System	22 Jan 2021 12:28:53
User entered '2'	System	19 Jan 2021 18:38:48
User entered '1'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered		
'USA-US106-2020-MRNA-1273-P301000011'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41



**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Easton'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Easton'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Beshears'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change:	(b) (4), (b) (6)	21 Jan 2021 18:36:08
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Beshears'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08



**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:37
User entered 'US'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 19:41:15
User entered '5'	System	29 Jan 2021 16:09:40
User entered '4'	System	25 Jan 2021 15:15:58
User entered '3'	System	22 Jan 2021 12:28:53
User entered '2'	System	19 Jan 2021 18:38:48
User entered '1'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
User entered '23/Dec/2020 09:27'	System	23 Dec 2020 14:27:27

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:46:24

**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.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:37
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered		
'USA-US106-2020-MRNA-1273-P301000011'	System	23 Dec 2020 14:26:41



US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Easton'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Easton'	System	23 Dec 2020 14:26:41



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Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Beshears'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change:	(b) (4), (b) (6)	21 Jan 2021 18:36:08
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Beshears'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:37
User entered 'US'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 19:41:15
User entered '5'	System	29 Jan 2021 16:09:40
User entered '4'	System	25 Jan 2021 15:15:58
User entered '3'	System	22 Jan 2021 12:28:53
User entered '2'	System	19 Jan 2021 18:38:48
User entered '1'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '19/Jan/2021 13:38'	(b) (4) System	19 Jan 2021 18:38:48



US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:46:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 18:38:48

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered		
'USA-US106-2020-MRNA-1273-P301000011'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41



US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Easton'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Easton'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Beshears'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change:	(b) (4), (b) (6)	21 Jan 2021 18:36:08
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Beshears'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:37
User entered 'US'	System	23 Dec 2020 14:27:27



**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 19:41:15
User entered '5'	System	29 Jan 2021 16:09:40
User entered '4'	System	25 Jan 2021 15:15:58
User entered '3'	System	22 Jan 2021 12:28:53
User entered '2'	System	19 Jan 2021 18:38:48
User entered '1'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '22/Jan/2021 12:28'	(b) (4) System	22 Jan 2021 12:28:53

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:46:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:15:42
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 12:28:53

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered		
'USA-US106-2020-MRNA-1273-P301000011'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41



**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Easton'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Easton'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Beshears'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change:	(b) (4), (b) (6)	21 Jan 2021 18:36:08
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Beshears'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08



**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:37
User entered 'US'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 19:41:15
User entered '5'	System	29 Jan 2021 16:09:40
User entered '4'	System	25 Jan 2021 15:15:58
User entered '3'	System	22 Jan 2021 12:28:53
User entered '2'	System	19 Jan 2021 18:38:48
User entered '1'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '25/Jan/2021 10:15'	(b) (4) System	25 Jan 2021 15:15:58

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:46:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 15:15:58

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'USA-US106-2020-MRNA-1273-P301000011'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41



**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Easton'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Easton'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Beshears'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change:	(b) (4), (b) (6)	21 Jan 2021 18:36:08
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Beshears'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08



**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:37
User entered 'US'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 19:41:15
User entered '5'	System	29 Jan 2021 16:09:40
User entered '4'	System	25 Jan 2021 15:15:58
User entered '3'	System	22 Jan 2021 12:28:53
User entered '2'	System	19 Jan 2021 18:38:48
User entered '1'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '29/Jan/2021 11:09'	(b) (4) System	29 Jan 2021 16:09:40

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:46:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:40:41
User entered 'I'	(b) (4), (b) (6)	29 Jan 2021 16:09:40

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered		
'USA-US106-2020-MRNA-1273-P301000011'	System	23 Dec 2020 14:26:41



US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:09:25
Un-reviewed for Safety.	System	28 Jan 2021 15:49:38
User entered 'No (N)'	System	28 Jan 2021 15:49:38
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 12:27:13
Un-reviewed for Safety.	System	21 Jan 2021 18:37:05
DataPoint Un-verified.	System	21 Jan 2021 18:37:05
User entered 'Yes (Y)'	System	21 Jan 2021 18:37:05
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'No (N)'	System	23 Dec 2020 14:26:41

US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Easton'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Easton'	System	23 Dec 2020 14:26:41



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Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:46:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered 'Beshears'	System	21 Jan 2021 18:37:05
Un-reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 18:36:08
User entered (b) (6) ' reason for change:	(b) (4), (b) (6)	21 Jan 2021 18:36:08
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:17
User entered 'Beshears'	System	23 Dec 2020 14:26:41

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:27:13
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 18:36:08

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 19:29:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 14:27:37
User entered 'US'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:46:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 19:41:15
User entered '5'	System	29 Jan 2021 16:09:40
User entered '4'	System	25 Jan 2021 15:15:58
User entered '3'	System	22 Jan 2021 12:28:53
User entered '2'	System	19 Jan 2021 18:38:48
User entered '1'	System	23 Dec 2020 14:27:27

**US3482094**

**Folder: SAE USA-US106-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 17:46:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
User entered '08/Mar/2021 13:41'	(b) (4) System	08 Mar 2021 19:41:15



US3482094

Folder: SAE USA-US106-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:46:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:50:17
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:23:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:42:12
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 19:41:15