

US3182114 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:31:10

All time stamps listed in this document are displayed in GMT

US3182114

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:18:45

Generated On: 09 Jun 2021 15:31:10

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[Participant ID](#)

US3182114

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

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US3182114

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Date of Informed Consent ( <i>dd MMM yyyy</i> )	31 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input 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) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Condition	LEFT THIGH MELANOMA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Condition	FREQUENT SINUS INFECTIONS
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Condition	SINUS SURGERY
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:37:31

Generated On: 09 Jun 2021 15:31:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	31 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	14:51 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 14:51
Height ( <i>xxx.x</i> )	176.0 cm
Weight ( <i>xxx.x</i> )	105.4 kg
BMI ( <i>xxx.x</i> )	34.02634 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:37:31

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 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) 15 Feb 2021 19:37:31

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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**

WORKING FROM HOME

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:37:31

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

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

What was the participant's randomization number? 100451

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 JUL 2020
Time of assessment (00:00-23:59)	14:51 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 14:51
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 JUL 2020
Time of assessment (00:00-23:59)	16:06 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 16:06
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 31 JUL 2020

What was the treatment time? (00:00-23:59) 15:31 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 15:31

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 JUL 2020
Collection time (00:00-23:59)	15:08 (24 HR)
Collection date and time (derived)	31 JUL 2020 15:08

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Collection date (dd MMM yyyy)			31 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:03	31 JUL 2020 15:03
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

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 15:31:10

**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

31 JUL 2020 16:02

PC Open Date & Time

31 JUL 2020 15:51

PC Close Date & Time

31 JUL 2020 18:21

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**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 97.6 °F

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

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

PC Time Stamp	31 JUL 2020 23:01
PC Open Date & Time	31 JUL 2020 19:16
PC Close Date & Time	01 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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**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

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

01 AUG 2020 12:40

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	02 AUG 2020 15:16
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**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

97.9 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

03 AUG 2020 12:07

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

04 AUG 2020 22:30

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**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

97.0 °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

05 AUG 2020 12:03

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 12:42

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

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

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

31 JUL 2020 16:04

PC Open Date & Time

31 JUL 2020 15:51

PC Close Date & Time

31 JUL 2020 18:21

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 23:02

PC Open Date & Time

31 JUL 2020 19:16

PC Close Date & Time

01 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 12:40

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59



US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 15:16

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**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

03 AUG 2020 12:07

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**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

04 AUG 2020 22:31

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**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

05 AUG 2020 12:03

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**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

06 AUG 2020 12:42

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**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 ☐

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 16:04
PC Open Date & Time	31 JUL 2020 15:51
PC Close Date & Time	31 JUL 2020 18:21

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**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 ☐



US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 23:01
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PC Open Date & Time	31 JUL 2020 19:16
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PC Close Date & Time	01 AUG 2020 11:59
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US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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 ☒

PRODUCTION RELEASE (v12.003

49 of 2722

EAB) (1725)

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 12:41
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2722

EAB) (1725)

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 15:17
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

53 of 2722

EAB) (1725)

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 12:07
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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

55 of 2722

EAB) (1725)



US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 22:31
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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

57 of 2722

EAB) (1725)

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 12:04
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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

59 of 2722

EAB) (1725)

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 12:42
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3182114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:08:57

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:08:57

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:08:57

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3182114

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:08:57

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:08:57

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:08:57

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 13:30
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	14:50 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:50
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	101 mmHg
Diastolic Blood Pressure units	MMHG

US3182114

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3182114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 14:15 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 14:15

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



US3182114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	31 AUG 2020
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Collection time (00:00-23:59)	13:58 (24 HR)
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Collection date and time (derived)	31 AUG 2020 13:58
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US3182114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:48	31 AUG 2020 13:48
Nasopharyngeal Swab 2	No		

US3182114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**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

98.4 °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

31 AUG 2020 14:48

PC Open Date & Time

31 AUG 2020 14:35

PC Close Date & Time

31 AUG 2020 17:05

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**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 97.9 °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 01 SEP 2020 10:47

PC Open Date & Time 31 AUG 2020 18:00

PC Close Date & Time 01 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**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

98.4 °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

02 SEP 2020 00:03

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:57

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

03 SEP 2020 19:10

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**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

98.1 °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

04 SEP 2020 13:06

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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**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 ☒

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

Yes ☐

No ☒

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

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PC Time Stamp 05 SEP 2020 12:00

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

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US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**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.

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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

06 SEP 2020 12:27

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

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

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

31 AUG 2020 14:49

PC Open Date & Time

31 AUG 2020 14:35

PC Close Date & Time

31 AUG 2020 17:05

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**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

01 SEP 2020 10:47

PC Open Date & Time

31 AUG 2020 18:00

PC Close Date & Time

01 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**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

02 SEP 2020 00:03

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**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

02 SEP 2020 12:58

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**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

03 SEP 2020 19:10

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**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

04 SEP 2020 13:06

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**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

05 SEP 2020 12:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**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

06 SEP 2020 12:27

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**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 ☐

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 14:49
PC Open Date & Time	31 AUG 2020 14:35
PC Close Date & Time	31 AUG 2020 17:05

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**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 ☐

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 10:48
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PC Open Date & Time	31 AUG 2020 18:00
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PC Close Date & Time	01 SEP 2020 11:59
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US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 00:03
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 12:58
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**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 ☒

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:10
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 13:06
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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

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EAB) (1725)



US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**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 ☒

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:27
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3182114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:08:57

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:08:57

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3182114

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:09:15

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:09:23

Generated On: 09 Jun 2021 15:31:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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	VISIT3

US3182114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:09:23

Generated On: 09 Jun 2021 15:31:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 14:15
Temperature (xxx.x)	99.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

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.*

US3182114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	28 SEP 2020
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Collection time (00:00-23:59)	14:29 (24 HR)
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Collection date and time (derived)	28 SEP 2020 14:29
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US3182114

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:09:16

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 SEP 2020 00:01:29
Patient Cloud Open Date & Time	30 SEP 2020 00:01
Patient Cloud Close Date & Time	04 OCT 2020 23:59

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

07 OCT 2020 02:08:57

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59



US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 OCT 2020 00:02:10
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 00:01:44
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 00:01:33

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 00:01:23

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 113
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	True
Headache	True
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	18 NOV 2020 00:02:15
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 08:24:42
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 00:10:08

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

29 NOV 2020 00:01:20

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59



US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

06 DEC 2020 00:01:22

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

15 DEC 2020 12:02:21

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 DEC 2020 12:01:39
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

29 DEC 2020 12:00:42

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

03 JAN 2021 00:01:46

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 00:02:19
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

17 JAN 2021 00:01:40

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

24 JAN 2021 00:01:49

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59



US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

31 JAN 2021 08:07:19

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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	07 FEB 2021 12:57:16
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 00:04:28

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

21 FEB 2021 00:19:33

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

28 FEB 2021 05:01:29

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

07 MAR 2021 00:02:34

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

14 MAR 2021 00:02:37

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 MAR 2021 00:25:07
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59



US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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

28 MAR 2021 21:26:05

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 APR 2021 21:39:03
Patient Cloud Open Date & Time	04 APR 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
145 of 2722	

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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

Date and time of submission

11 APR 2021 00:02:18

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 01:40:25

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 22:34:35

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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

Date and time of submission

02 MAY 2021 00:02:31

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 MAY 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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"/>



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

18 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 397

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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="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"/>



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	26 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	03 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	07 OCT 2021 23:59
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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59
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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	24 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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"/>



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

13 FEB 2022 00:01

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17 FEB 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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27 FEB 2022 00:01

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03 MAR 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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

**US3182114**

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

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**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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27 MAR 2022 00:01

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31 MAR 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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="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"/>

**US3182114**

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

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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 APR 2022 00:01

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07 APR 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 649

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

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

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

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

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

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



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°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="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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 <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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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="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°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="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"/>



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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="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"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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[Patient Cloud Close Date & Time](#)

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15 SEP 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

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US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

**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 ☐



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59

US3182114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

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

US3182114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:31:10

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		28 FEB 2021 05:01:40

US3182114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3182114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Mar 2021 21:42:07

Generated On: 09 Jun 2021 15:31:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 13:36
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182114

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3182114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 15:34:47

Generated On: 09 Jun 2021 15:31:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	23 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	14:05 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	23 FEB 2021 14:05
------------------------------------	-------------------



US3182114

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 15:44:39

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 15:44:39

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3182114**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

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*

**US3182114**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

Date of Contact	18 NOV 2020
Time of Contact	09:30
Date and Time of Contact (derived)	18 NOV 2020 09:30
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>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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	95 %	
O2 Saturation Units	%	
Temperature	98.8 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 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"/>



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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	89 %	
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 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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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	100 %
---------------	-------

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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EAB) (1725)

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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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US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

Symptom Day

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

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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	99 %	
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"/>

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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"/>



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

Symptom Day

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

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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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US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

Symptom Day

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

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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"/>

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 (12)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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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Form: Symptom Log (13)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 (13)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 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 (13)

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Generated On: 09 Jun 2021 15:31:10

	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 18 Nov 2020

Form: Symptom Log (13)

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Generated On: 09 Jun 2021 15:31:10

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 type="radio"/>
	Mild	<input checked="" 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) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 09 Mar 2021 04:18:46

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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 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 (14)

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Generated On: 09 Jun 2021 15:31:10

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (15)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 (15)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>



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Form: Symptom Log (15)

Data signed: (b) (4) 09 Mar 2021 04:18:46

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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 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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Form: Symptom Log (15)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 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 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 (16)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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 18 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 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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	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 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 18 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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

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US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

	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 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"/>

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

Nasal Congestion

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3182114

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 10 Mar 2021 21:45:38

Generated On: 09 Jun 2021 15:31:10

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 NOV 2020
Day 5	Yes	22 NOV 2020
Day 7	Yes	24 NOV 2020
Day 9	Yes	26 NOV 2020
Day 14	Yes	02 DEC 2020
Day 21	Yes	08 DEC 2020
Day 28	NA (COVID-19 Negative)	

US3182114

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

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

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

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)	15:06 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 15:06
Height (xxx.x)	175.3 cm
Weight (xxx.x)	102.06 kg
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182114

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

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.*



US3182114

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 NOV 2020

US3182114

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	27 JAN 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	UNBLND_DECIDE
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US3182114

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

Form: Unblinding

Data signed: (b) (4) 10 Mar 2021 21:45:49

Generated On: 09 Jun 2021 15:31:10

Date of updated informed consent ( <i>dd MMM yyyy</i> )	27 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> )	27 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 checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3182114

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Height	176.0 cm
Weight	108.4 kg
BMI (xxx.x)	34.99483

US3182114

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Height	176.0 cm
Weight	108.4 kg
BMI (xxx.x)	34.99483
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)	27 JAN 2021
Time of assessment (00:00-23:59)	15:03 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 15:03
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3182114

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Height	176.0 cm
Weight	108.4 kg
BMI (xxx.x)	34.99483
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)	27 JAN 2021
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 15:40
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3182114

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

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JAN 2021

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

US3182114

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

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 27 JAN 2021

What was the treatment time? (00:00-23:59) 15:10 (24 HR)

Treatment Date and Time (derived) 27 JAN 2021 15:10

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



US3182114

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

15:00 (24 HR)

Collection date and time (derived)

27 JAN 2021 15:00

US3182114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	14:46
Collection Date and Time (derived)	27 JAN 2021 14:46

US3182114

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

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:18:47

Generated On: 09 Jun 2021 15:31:10

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

US3182114

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 15:34:47

Generated On: 09 Jun 2021 15:31:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	23 FEB 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	OLD29
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US3182114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 15:34:47

Generated On: 09 Jun 2021 15:31:10

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)	23 FEB 2021
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 13:36
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3182114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 15:34:47

Generated On: 09 Jun 2021 15:31:10

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)	23 FEB 2021
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 15:01
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG



US3182114

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 15:34:47

Generated On: 09 Jun 2021 15:31:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3182114

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 15:34:47

Generated On: 09 Jun 2021 15:31:10

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 14:31 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 14:31

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

What was the frequency of the study treatment dosing? ONCE

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

US3182114

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 15:34:47

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 15:34:47

Generated On: 09 Jun 2021 15:31:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182114

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 15:34:47

Generated On: 09 Jun 2021 15:31:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182114

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Mar 2021 21:42:07

Generated On: 09 Jun 2021 15:31:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3182114

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Mar 2021 21:42:07

Generated On: 09 Jun 2021 15:31:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	13:47 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 13:47
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 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)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182114

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Mar 2021 21:42:07

Generated On: 09 Jun 2021 15:31:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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



US3182114

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:31:18

Generated On: 09 Jun 2021 15:31:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	14:06 (24 HR)
Collection date and time (derived)	22 MAR 2021 14:06

US3182114

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 15:25:33

Generated On: 09 Jun 2021 15:31:10

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3182114

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 17:43:51

Generated On: 09 Jun 2021 15:31:10

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)

16 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 17:43:51

Generated On: 09 Jun 2021 15:31:10

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 17:43:51

Generated On: 09 Jun 2021 15:31:10

AEID

Adverse event

SINUS CONGESTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

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)

US3182114

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 17:43:51

Generated On: 09 Jun 2021 15:31:10

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 17:43:51

Generated On: 09 Jun 2021 15:31:10

AEID	USA-US075-2021-MRNA-1273-P30 1000013
Adverse event	ABDOMINAL PAIN
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)	05 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 17:43:51

Generated On: 09 Jun 2021 15:31:10

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	



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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 17:43:51

Generated On: 09 Jun 2021 15:31:10

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CLINICAL SITE STAFF CALLED  
SUBJECT AFTER WE RECEIVED  
AN ALERT THAT SUBJECT  
REPORTED IN HIS DAY 236  
DIARY FORM THAT HE HAD  
CONTACT WITH HIS  
HEALTHCARE PROVIDER.  
SUBJECT CONFIRMED THAT HE  
IS CURRENTLY ADMITTED TO  
HOSPITAL. SUBJECT STATES HE  
ACTUALLY PRESENTED TO ER  
ON 05-APR-2021 WITH  
COMPLAINTS OF FEVER AND  
CHILLS. SUBJECT WAS  
ADMITTED ON 06-APR-2021.  
SUBJECT REPORTS SYMPTOMS  
OF ABDOMINAL PAIN, FEVER,  
FATIGUE. INFORMATION WILL  
BE UPDATED WHEN RECORDS  
ARE RECEIVED AFTER  
DISCHARGE.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 17:43:51

Generated On: 09 Jun 2021 15:31:10

AEID	
Adverse event	CALF TEAR
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (4)

Data signed: (b) (4) 09 Apr 2021 17:43:51

Generated On: 09 Jun 2021 15:31:10

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

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

Yes ☒

No ☐

---

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

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US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
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) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

Name of Medication TEMAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 30

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) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

Name of Medication TRUVADA

Prophylaxis Yes ☒  
No ☐

Indication HIV PREP

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

Name of Medication VIIBRYD

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	03 AUG 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="radio"/>	
	No <input 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="radio"/>	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

Name of Medication SUDAFED (PSEUDOEPHEDRINE)

Prophylaxis Yes ☐  
No ☒

Indication SINUS CONGESTION

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

444 of 2722

EAB) (1725)

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

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 ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

446 of 2722

EAB) (1725)

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 12:47:31

Generated On: 09 Jun 2021 15:31:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	



US3182114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:18:46

Generated On: 09 Jun 2021 15:31:10

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3182114

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:31:10

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 ☐

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 17:43:52

Generated On: 09 Jun 2021 15:31:10

SAEID	USA-US075-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 17:43:52

Generated On: 09 Jun 2021 15:31:10

SAEID	USA-US075-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	09/APR/2021 12:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3182114 (Prod: Rapid Medical Research Inc - ERN-PPDS)

**US3182114**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:31:10**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'US3182114'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:04:25

**US3182114**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	31 Jul 2020 19:46:30

US3182114

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:10

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:04:26



**US3182114**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Clinic (Clinic)'	Brooke Glivar (b) (4)	31 Jul 2020 19:46:30

**US3182114**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'SCRN'	System	31 Jul 2020 19:46:30

US3182114

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered (b) (6) 1967'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:04:27

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '53'	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'YEARS'	System	05 Aug 2020 15:33:59

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '53'	System	31 Jul 2020 19:46:45

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Male (M)'	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59



**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'I'	Cassie Uminski	05 Aug 2020 15:33:59

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59
	(b) (4)	

**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59



**US3182114**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:31:10**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:33:59

US3182114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:10

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '31 Jul 2020'	Brooke Glivar (b) (4)	31 Jul 2020 19:46:45

**US3182114**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:31:10**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jul 2020'	System	31 Jul 2020 19:46:45

**US3182114**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:31:10**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '2020'	System	31 Jul 2020 19:46:45

**US3182114**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:31:10**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Amendment 1 (1)'	Brooke Glivar (b) (4)	31 Jul 2020 19:46:45

US3182114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:10

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	Brooke Glivar	31 Jul 2020 19:46:45

**US3182114**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:31:10**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty.	Brooke Glivar (b) (4)	31 Jul 2020 19:46:45

**US3182114**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:31:10**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty.	Brooke Glivar (b) (4)	31 Jul 2020 19:46:45



**US3182114**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:31:10**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	Brooke Glivar (b) (4)	31 Jul 2020 19:46:45

US3182114

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:10

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:04:26

**US3182114**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:31:10**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'I'	System	31 Jul 2020 19:46:51

**US3182114**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 15:31:10**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	31 Jul 2020 19:46:51

US3182114

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:31:10

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:36

US3182114

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 15:39:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 15:39:55
Data point term sent to Coder	System	05 Aug 2020 15:39:22
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:38:50

**US3182114**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 2015'	Cassie Uminski	05 Aug 2020 15:38:50

**US3182114**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:50



**US3182114**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:50

**US3182114**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:31:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:38:50

**US3182114**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:50

**US3182114**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 2015'	System	05 Aug 2020 15:38:50

**US3182114**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '2015'	System	05 Aug 2020 15:38:50

**US3182114**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered empty.	System	05 Aug 2020 15:38:50

**US3182114**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered empty.	System	05 Aug 2020 15:38:50

US3182114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:40:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:40:57
Data point term sent to Coder	System	05 Aug 2020 15:40:22
User entered 'High cholesterol'	Cassie Uminski (b) (4)	05 Aug 2020 15:39:33



US3182114

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:10

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 2015'	Cassie Uminski	05 Aug 2020 15:39:33

**US3182114**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:39:33

**US3182114**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	Cassie Uminski	05 Aug 2020 15:39:33

**US3182114**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:31:10**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:39:33

**US3182114**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:39:33

**US3182114**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 2015'	System	05 Aug 2020 15:39:33

**US3182114**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '2015'	System	05 Aug 2020 15:39:33

**US3182114**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered empty.	System	05 Aug 2020 15:39:33



**US3182114**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered empty.	System	05 Aug 2020 15:39:33

US3182114

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:40:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:40:57
Data point term sent to Coder	System	05 Aug 2020 15:40:22
User entered 'Hypertension'	Cassie Uminski (b) (4)	05 Aug 2020 15:39:43
	(b) (4)	

**US3182114**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 2019'	Cassie Uminski (b) (4)	05 Aug 2020 15:39:43

**US3182114**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	(b) (4)	
	Cassie Uminski (b) (4)	05 Aug 2020 15:39:43
	(b) (4)	

**US3182114**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:39:43

**US3182114**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:31:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:39:43

**US3182114**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:39:43

**US3182114**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 2019'	System	05 Aug 2020 15:39:43



**US3182114**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '2019'	System	05 Aug 2020 15:39:43

**US3182114**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered empty.	System	05 Aug 2020 15:39:43

**US3182114**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered empty.	System	05 Aug 2020 15:39:43

US3182114

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Skin melanoma - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Aug 2020 00:17:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 00:17:00
Data point term sent to Coder	System	05 Aug 2020 15:40:23
User entered 'Left thigh melanoma'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:40:03

**US3182114**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 2000'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:03

**US3182114**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:03

**US3182114**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:40:03

**US3182114**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:31:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 2000'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:03



**US3182114**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:03

**US3182114**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 2000'	System	05 Aug 2020 15:40:03

**US3182114**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '2000'	System	05 Aug 2020 15:40:03

**US3182114**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 2000'	System	05 Aug 2020 15:40:03

**US3182114**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '2000'	System	05 Aug 2020 15:40:03

US3182114

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:40:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:40:57
Data point term sent to Coder	System	05 Aug 2020 15:40:25
User entered 'Depression'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:15

**US3182114**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 2015'	Cassie Uminski	05 Aug 2020 15:40:15

**US3182114**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:15



**US3182114**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	Cassie Uminski	05 Aug 2020 15:40:15

**US3182114**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:31:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:40:15

**US3182114**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:15

**US3182114**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 2015'	System	05 Aug 2020 15:40:15

**US3182114**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '2015'	System	05 Aug 2020 15:40:15

**US3182114**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered empty.	System	05 Aug 2020 15:40:15

**US3182114**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered empty.	System	05 Aug 2020 15:40:15

US3182114

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:41:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:41:59
Data point term sent to Coder	System	05 Aug 2020 15:41:27
User entered 'Anxiety'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:28
	(b) (4)	



**US3182114**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 2015'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:28

**US3182114**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:28

**US3182114**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:40:28

**US3182114**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:31:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:40:28

**US3182114**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:28

**US3182114**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 2015'	System	05 Aug 2020 15:40:28

**US3182114**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '2015'	System	05 Aug 2020 15:40:28

**US3182114**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered empty.	System	05 Aug 2020 15:40:28



**US3182114**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered empty.	System	05 Aug 2020 15:40:28

US3182114

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:41:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:41:59
Data point term sent to Coder	System	05 Aug 2020 15:41:25
User entered 'Frequent sinus infections'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:44

**US3182114**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 1995'	Cassie Uminski	05 Aug 2020 15:40:44

**US3182114**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:44

**US3182114**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:40:44

**US3182114**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:31:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 1995'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:44

**US3182114**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:44

**US3182114**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 1995'	System	05 Aug 2020 15:40:44



**US3182114**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '1995'	System	05 Aug 2020 15:40:44

**US3182114**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 1995'	System	05 Aug 2020 15:40:44

**US3182114**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '1995'	System	05 Aug 2020 15:40:44

US3182114

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:41:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:41:59
Data point term sent to Coder	System	05 Aug 2020 15:41:26
User entered 'Sinus surgery'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:59

**US3182114**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 1995'	Cassie Uminski	05 Aug 2020 15:40:59

US3182114

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:40:59

**US3182114**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	05 Aug 2020 15:40:59
	(b) (4)	

**US3182114**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:31:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'un UNK 1995'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:59



**US3182114**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:40:59

**US3182114**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 1995'	System	05 Aug 2020 15:40:59

**US3182114**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '1995'	System	05 Aug 2020 15:40:59

**US3182114**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'Jan 1995'	System	05 Aug 2020 15:40:59

**US3182114**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '1995'	System	05 Aug 2020 15:40:59

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:34:50

**US3182114**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '31 Jul 2020'	Cassie Uminski (b) (4)	05 Aug 2020 15:34:50

**US3182114**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '14:51'	Cassie Uminski (b) (4)	05 Aug 2020 15:34:50



**US3182114**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered '31 Jul 2020 14:51'	System	05 Aug 2020 15:34:50

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '176.0' cm	(b) (4) Cassie Uminski (b) (4)	05 Aug 2020 15:34:50
DataPoint set to visible.	(b) (4) System	31 Jul 2020 19:46:51

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '105.4' kg	(b) (4) Cassie Uminski (b) (4)	05 Aug 2020 15:34:50
DataPoint set to visible.	(b) (4) System	31 Jul 2020 19:46:51

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
Amendment Manager: User entered '34.02634'	System	16 Sep 2020 23:39:57
User entered '34.0'	System	05 Aug 2020 15:34:50
DataPoint set to visible.	System	31 Jul 2020 19:46:51

**US3182114**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'kg/m2'	System	05 Aug 2020 15:34:50
DataPoint set to visible.	System	31 Jul 2020 19:46:51

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Aug 2020 15:34:50

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User closed query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 18:07:22
Query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	28 Sep 2020 12:48:32
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	28 Sep 2020 12:48:27
User opened query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 02:48:34
User entered 'Other (Other)'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:34:50

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	28 Sep 2020 12:48:27
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	05 Aug 2020 15:34:50



US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:34:50

**US3182114**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'bpm'	System	05 Aug 2020 15:34:50

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Aug 2020 15:34:50

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'breaths/min'	System	05 Aug 2020 15:34:50

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Aug 2020 15:34:50

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'mmHg'	System	05 Aug 2020 15:34:50

**US3182114**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Aug 2020 15:34:50

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User entered 'mmHg'	System	05 Aug 2020 15:34:50



US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16

US3182114

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16

**US3182114**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	05 Aug 2020 15:36:39
	(b) (4)	

US3182114

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:39:32
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 18:28:10
User entered '31 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:36:39

US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:38:12

US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:38:12

US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12

US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12



US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	Cassie Uminski	05 Aug 2020 15:38:12

US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12

US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12

US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12

US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:38:12

US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12

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Folder: Screening

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12

**US3182114**

**Folder: Screening**

**Form: Risk of Exposure**

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**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12



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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'Working from home'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered 'I'	(b) (4)	
	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12

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Folder: Screening

Form: Risk of Exposure

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**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12

US3182114

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	(b) (4)	05 Aug 2020 15:38:12
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:38:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:38:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:38:12



**US3182114**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:31:10**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:06:16
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:37:32
User entered empty.	(b) (4)	05 Aug 2020 15:38:12
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski	05 Aug 2020 15:37:42

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Jul 2020'	Cassie Uminski (b) (4)	05 Aug 2020 15:37:42

US3182114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	05 Aug 2020 15:37:42

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'VISIT1'	System	05 Aug 2020 15:37:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:24:36

US3182114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:10

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:32:49
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:32:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 19:24:36
User entered '100451' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:24:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:10

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:24:36



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:10

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)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:36:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:10

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)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:36:19

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:31:10**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:36:19

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:31:10**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'No (N)'	Cassie Uminski	05 Aug 2020 15:36:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:10

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'No (N)'	Cassie Uminski	05 Aug 2020 15:36:19

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:31:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:31:10**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44



**US3182114**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:31:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Jul 2020'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '14:51'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '31 Jul 2020 14:51'	System	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '98.9' F	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '77'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'bpm'	System	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '16'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'breaths/min'	System	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '117'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'mmHg'	System	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '80'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'mmHg'	System	05 Aug 2020 15:35:44

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:31:10**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:31:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Jul 2020'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 21:00:13
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).		05 Aug 2020 15:35:44
User entered '16:06'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '31 Jul 2020 16:06'	System	05 Aug 2020 15:35:44



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '97.9' F	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '79'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'bpm'	System	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '16'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'breaths/min'	System	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '133'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44



US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'mmHg'	System	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '82'	Cassie Uminski (b) (4)	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'mmHg'	System	05 Aug 2020 15:35:44

US3182114

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'No (N)'	Cassie Uminski	05 Aug 2020 15:36:45

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:36:45

US3182114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Brooke Glivar (b) (4)	31 Jul 2020 19:47:32

US3182114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	Brooke Glivar (b) (4)	31 Jul 2020 19:47:32

US3182114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

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 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	Brooke Glivar (b) (4)	31 Jul 2020 19:47:32



US3182114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 19:47:32

US3182114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Jul 2020'	Brooke Glivar (b) (4)	31 Jul 2020 19:47:32

US3182114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '15:31'	Brooke Glivar (b) (4)	31 Jul 2020 19:47:32

US3182114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '31 Jul 2020 15:31'	System	31 Jul 2020 19:47:32

US3182114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Left Arm (LEFT ARM)'	Brooke Glivar (b) (4)	31 Jul 2020 19:47:32

US3182114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'ONCE'	System	31 Jul 2020 19:47:32

US3182114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 19:47:32

US3182114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:37:25



US3182114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Jul 2020'	Cassie Uminski (b) (4)	05 Aug 2020 15:37:25

US3182114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '15:08'	Cassie Uminski (b) (4)	05 Aug 2020 15:37:25

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '31 Jul 2020 15:08'	System	05 Aug 2020 15:37:25

US3182114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:31:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Jul 2020'	Cassie Uminski (b) (4)	05 Aug 2020 15:37:11

US3182114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	05 Aug 2020 15:37:11
	(b) (4)	

US3182114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:37:11

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:31:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '15:03'	Cassie Uminski (b) (4)	05 Aug 2020 15:37:11

US3182114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '31 Jul 2020 15:03'	System	05 Aug 2020 15:37:11



US3182114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	05 Aug 2020 15:37:11
	(b) (4)	

US3182114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'No (N)'	Cassie Uminski	05 Aug 2020 15:37:11

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:31:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:37:11

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered empty.	System	05 Aug 2020 15:37:11

US3182114

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:31:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski	05 Aug 2020 15:37:32

**US3182114**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'I'	System	05 Aug 2020 15:37:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:01:18', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '307c98a1-c197-4f39-8d9e-fe099f4e6c55' User entered 'Yes (Y)'	System	31 Jul 2020 20:02:52
	System	31 Jul 2020 20:02:52



US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:02:33', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '307c98a1-c197-4f39-8d9e-fe099f4e6c55' User entered '97.9'	System	31 Jul 2020 20:02:52
	System	31 Jul 2020 20:02:52

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:02:46', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '307c98a1-c197-4f39-8d9e-fe099f4e6c55'	System	31 Jul 2020 20:02:52
User entered 'No (N)'	System	31 Jul 2020 20:02:52

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:02:51', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '307c98a1-c197-4f39-8d9e-fe099f4e6c55' User entered '31 Jul 2020 16:02'	System	31 Jul 2020 20:02:52
	System	31 Jul 2020 20:02:52

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Jul 2020 15:51'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Jul 2020 18:21'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:00:51', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9ea49211-209e-4abf-8f2e-beb40af727bc' User entered 'Yes (Y)'	System	01 Aug 2020 03:01:11
	System	01 Aug 2020 03:01:11

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:01', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9ea49211-209e-4abf-8f2e-beb40af727bc' User entered '97.6'	System	01 Aug 2020 03:01:11
	System	01 Aug 2020 03:01:11



US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:05', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9ea49211-209e-4abf-8f2e-beb40af727bc' User entered 'No (N)'	System	01 Aug 2020 03:01:11
	System	01 Aug 2020 03:01:11

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:09', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9ea49211-209e-4abf-8f2e-beb40af727bc' User entered '31 Jul 2020 23:01'	System	01 Aug 2020 03:01:11
	System	01 Aug 2020 03:01:11

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Jul 2020 19:16'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 2'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:39:49', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '040d8d20-faf0-4b8a-a829-19a074cfc319' User entered 'Yes (Y)'	System	01 Aug 2020 16:40:04
	System	01 Aug 2020 16:40:04

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:39:55', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '040d8d20-faf0-4b8a-a829-19a074cfc319' User entered '96.9'	System	01 Aug 2020 16:40:04
	System	01 Aug 2020 16:40:04

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:39:58', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '040d8d20-faf0-4b8a-a829-19a074cfc319'	System	01 Aug 2020 16:40:04
User entered 'No (N)'	System	01 Aug 2020 16:40:04



**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '040d8d20-faf0-4b8a-a829-19a074cfc319'	System	01 Aug 2020 16:40:04
User entered '01 Aug 2020 12:40'	System	01 Aug 2020 16:40:04

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 3'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:15:50', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0c4620ea-35d3-4927-8a1c-d9fe9d42e0a7' User entered 'Yes (Y)'	System	02 Aug 2020 19:16:18
	System	02 Aug 2020 19:16:18

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:15:54', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0c4620ea-35d3-4927-8a1c-d9fe9d42e0a7' User entered '97.4'	System	02 Aug 2020 19:16:18
	System	02 Aug 2020 19:16:18

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:01', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0c4620ea-35d3-4927-8a1c-d9fe9d42e0a7'	System	02 Aug 2020 19:16:18
User entered 'Yes (Y)'	System	02 Aug 2020 19:16:18

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 09:28:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:12', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0c4620ea-35d3-4927-8a1c-d9fe9d42e0a7' User entered '1'	Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 20:08:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	02 Aug 2020 19:16:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:12', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0c4620ea-35d3-4927-8a1c-d9fe9d42e0a7' User entered '1'	System	02 Aug 2020 19:16:18
User entered '1'	System	02 Aug 2020 19:16:18



US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:12', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0c4620ea-35d3-4927-8a1c-d9fe9d42e0a7' User entered '0'	System	02 Aug 2020 19:16:18
	System	02 Aug 2020 19:16:18

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0c4620ea-35d3-4927-8a1c-d9fe9d42e0a7' User entered '02 Aug 2020 15:16'	System	02 Aug 2020 19:16:18
	System	02 Aug 2020 19:16:18

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 4'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:06:43', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f788535a-2a8a-4c6e-bc73-d829d0a94b75'	System	03 Aug 2020 16:07:08
User entered 'Yes (Y)'	System	03 Aug 2020 16:07:08

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:06:47', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f788535a-2a8a-4c6e-bc73-d829d0a94b75' User entered '97.9'	System	03 Aug 2020 16:07:08
	System	03 Aug 2020 16:07:08

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:06:51', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f788535a-2a8a-4c6e-bc73-d829d0a94b75'	System	03 Aug 2020 16:07:08
User entered 'Yes (Y)'	System	03 Aug 2020 16:07:08



US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	(b) (4)	12 Nov 2020 09:28:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Cassie Uminski (b) (4)	06 Nov 2020 20:08:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:02', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f788535a-2a8a-4c6e-bc73-d829d0a94b75'	(b) (4)	
User entered '1'	System	03 Aug 2020 16:07:08
	System	03 Aug 2020 16:07:08
	System	03 Aug 2020 16:07:08

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:02', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f788535a-2a8a-4c6e-bc73-d829d0a94b75' User entered '0'	System	03 Aug 2020 16:07:08
	System	03 Aug 2020 16:07:08

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:06', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f788535a-2a8a-4c6e-bc73-d829d0a94b75'	System	03 Aug 2020 16:07:08
User entered '03 Aug 2020 12:07'	System	03 Aug 2020 16:07:08

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 5'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:30:49', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c3489d7e-5a8b-416f-b3e0-fb11cf02be71' User entered 'Yes (Y)'	System	05 Aug 2020 02:31:01
	System	05 Aug 2020 02:31:01

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:30:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c3489d7e-5a8b-416f-b3e0-fb11cf02be71' User entered '97.7'	System	05 Aug 2020 02:31:01
	System	05 Aug 2020 02:31:01



US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:30:55', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c3489d7e-5a8b-416f-b3e0-fb11cf02be71'	System	05 Aug 2020 02:31:01
User entered 'No (N)'	System	05 Aug 2020 02:31:01

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:30:57', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c3489d7e-5a8b-416f-b3e0-fb11cf02be71'	System	05 Aug 2020 02:31:01
User entered '04 Aug 2020 22:30'	System	05 Aug 2020 02:31:01

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 6'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:03:35', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0cb1b843-c9e2-4778-a2b0-f1d0a2977c8a' User entered 'Yes (Y)'	System	05 Aug 2020 16:03:49
	System	05 Aug 2020 16:03:49

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:03:41', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0cb1b843-c9e2-4778-a2b0-f1d0a2977c8a' User entered '97.0'	System	05 Aug 2020 16:03:49
	System	05 Aug 2020 16:03:49

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:03:44', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0cb1b843-c9e2-4778-a2b0-f1d0a2977c8a' User entered 'No (N)'	System	05 Aug 2020 16:03:49
	System	05 Aug 2020 16:03:49



US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:03:46', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0cb1b843-c9e2-4778-a2b0-f1d0a2977c8a' User entered '05 Aug 2020 12:03'	System	05 Aug 2020 16:03:49
	System	05 Aug 2020 16:03:49

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 7'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:41:51', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '1b92369f-c571-4f58-9c83-cd19c401e076' User entered 'Yes (Y)'	System	06 Aug 2020 16:42:13
	System	06 Aug 2020 16:42:13

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:41:54', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '1b92369f-c571-4f58-9c83-cd19c401e076' User entered '97.6'	System	06 Aug 2020 16:42:13
	System	06 Aug 2020 16:42:13

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:06', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '1b92369f-c571-4f58-9c83-cd19c401e076'	System	06 Aug 2020 16:42:13
User entered 'No (N)'	System	06 Aug 2020 16:42:13

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:09', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '1b92369f-c571-4f58-9c83-cd19c401e076' User entered '06 Aug 2020 12:42'	System	06 Aug 2020 16:42:13
	System	06 Aug 2020 16:42:13



**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:03:53', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cb01babe-4541-4f2b-9974-a33277dfd6d0'	System	31 Jul 2020 20:04:21
User entered 'None (1)'	System	31 Jul 2020 20:04:21

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:03:56', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cb01babe-4541-4f2b-9974-a33277dfd6d0' User entered 'No (N)'	System	31 Jul 2020 20:04:21
	System	31 Jul 2020 20:04:21

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:03:58', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cb01babe-4541-4f2b-9974-a33277dfd6d0' User entered 'No (N)'	System	31 Jul 2020 20:04:21
	System	31 Jul 2020 20:04:21

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:04:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cb01babe-4541-4f2b-9974-a33277dfd6d0'	System	31 Jul 2020 20:04:21
User entered 'None (1)'	System	31 Jul 2020 20:04:21

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:04:19', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cb01babe-4541-4f2b-9974-a33277dfd6d0' User entered '31 Jul 2020 16:04'	System	31 Jul 2020 20:04:21
	System	31 Jul 2020 20:04:21



US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Jul 2020 15:51'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Jul 2020 18:21'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:59', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1d8d331-a190-4d6f-a128-434cc8f1328b' User entered 'None (1)'	System	01 Aug 2020 03:02:12
	System	01 Aug 2020 03:02:12

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:02:01', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1d8d331-a190-4d6f-a128-434cc8f1328b' User entered 'No (N)'	System	01 Aug 2020 03:02:12
	System	01 Aug 2020 03:02:12

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:02:04', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1d8d331-a190-4d6f-a128-434cc8f1328b' User entered 'No (N)'	System	01 Aug 2020 03:02:12
	System	01 Aug 2020 03:02:12

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:02:06', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1d8d331-a190-4d6f-a128-434cc8f1328b' User entered 'None (1)'	System	01 Aug 2020 03:02:12
	System	01 Aug 2020 03:02:12

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:02:09', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1d8d331-a190-4d6f-a128-434cc8f1328b' User entered '31 Jul 2020 23:02'	System	01 Aug 2020 03:02:12
	System	01 Aug 2020 03:02:12



**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Jul 2020 19:16'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 2'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:13', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '73ce43a1-6fbc-4183-9922-0e526676bf3d' User entered 'None (1)'	System	01 Aug 2020 16:40:46
	System	01 Aug 2020 16:40:46

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '73ce43a1-6fbc-4183-9922-0e526676bf3d' User entered 'No (N)'	System	01 Aug 2020 16:40:46
	System	01 Aug 2020 16:40:46

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:21', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '73ce43a1-6fbc-4183-9922-0e526676bf3d' User entered 'Yes (Y)'	System	01 Aug 2020 16:40:46
	System	01 Aug 2020 16:40:46

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:34', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '73ce43a1-6fbc-4183-9922-0e526676bf3d' User entered '2'	System	01 Aug 2020 16:40:46
	System	01 Aug 2020 16:40:46

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:42', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '73ce43a1-6fbc-4183-9922-0e526676bf3d' User entered 'None (1)'	System	01 Aug 2020 16:40:46
	System	01 Aug 2020 16:40:46



**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:44', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '73ce43a1-6fbc-4183-9922-0e526676bf3d' User entered '01 Aug 2020 12:40'	System	01 Aug 2020 16:40:46
	System	01 Aug 2020 16:40:46

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 3'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:28', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8e24bb08-c33e-49c1-8e17-a57c0c832a36'	System	02 Aug 2020 19:16:48
User entered 'None (1)'	System	02 Aug 2020 19:16:48

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:32', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8e24bb08-c33e-49c1-8e17-a57c0c832a36' User entered 'No (N)'	System	02 Aug 2020 19:16:48
	System	02 Aug 2020 19:16:48

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:39', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8e24bb08-c33e-49c1-8e17-a57c0c832a36'	System	02 Aug 2020 19:16:48
User entered 'Yes (Y)'	System	02 Aug 2020 19:16:48

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:42', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8e24bb08-c33e-49c1-8e17-a57c0c832a36' User entered '2'	System	02 Aug 2020 19:16:48
	System	02 Aug 2020 19:16:48



US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:45', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8e24bb08-c33e-49c1-8e17-a57c0c832a36' User entered 'None (1)'	System	02 Aug 2020 19:16:48
	System	02 Aug 2020 19:16:48

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:47', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8e24bb08-c33e-49c1-8e17-a57c0c832a36' User entered '02 Aug 2020 15:16'	System	02 Aug 2020 19:16:48
	System	02 Aug 2020 19:16:48

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 4'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:10', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ae03a53f-4432-426b-8e52-af86fb3b2813'	System	03 Aug 2020 16:07:21
User entered 'None (1)'	System	03 Aug 2020 16:07:21

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:12', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ae03a53f-4432-426b-8e52-af86fb3b2813'	System	03 Aug 2020 16:07:21
User entered 'No (N)'	System	03 Aug 2020 16:07:21

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:14', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ae03a53f-4432-426b-8e52-af86fb3b2813' User entered 'No (N)'	System	03 Aug 2020 16:07:21
	System	03 Aug 2020 16:07:21



US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ae03a53f-4432-426b-8e52-af86fb3b2813'	System	03 Aug 2020 16:07:21
User entered 'None (1)'	System	03 Aug 2020 16:07:21

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:19', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ae03a53f-4432-426b-8e52-af86fb3b2813' User entered '03 Aug 2020 12:07'	System	03 Aug 2020 16:07:21
	System	03 Aug 2020 16:07:21

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 5'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:04', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a22cf4e3-cef0-48e7-a8c8-fdfe298dda09'	System	05 Aug 2020 02:31:13
User entered 'None (1)'	System	05 Aug 2020 02:31:13

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:06', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a22cf4e3-cef0-48e7-a8c8-fdfe298dda09'	System	05 Aug 2020 02:31:13
User entered 'No (N)'	System	05 Aug 2020 02:31:13

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:08', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a22cf4e3-cef0-48e7-a8c8-fdfe298dda09'	System	05 Aug 2020 02:31:13
User entered 'No (N)'	System	05 Aug 2020 02:31:13



US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:09', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a22cf4e3-cef0-48e7-a8c8-fdfe298dda09'	System	05 Aug 2020 02:31:13
User entered 'None (1)'	System	05 Aug 2020 02:31:13

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:12', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a22cf4e3-cef0-48e7-a8c8-fdfe298dda09'	System	05 Aug 2020 02:31:13
User entered '04 Aug 2020 22:31'	System	05 Aug 2020 02:31:13

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 6'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:03:49', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '333b153e-dae5-4136-b975-23c6472909aa' User entered 'None (1)'	System	05 Aug 2020 16:04:25
	System	05 Aug 2020 16:04:25

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:03:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '333b153e-dae5-4136-b975-23c6472909aa'	System	05 Aug 2020 16:04:25
User entered 'No (N)'	System	05 Aug 2020 16:04:25

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:03:54', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '333b153e-dae5-4136-b975-23c6472909aa'	System	05 Aug 2020 16:04:25
User entered 'No (N)'	System	05 Aug 2020 16:04:25



US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:03:55', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '333b153e-dae5-4136-b975-23c6472909aa' User entered 'None (1)'	System	05 Aug 2020 16:04:25
	System	05 Aug 2020 16:04:25

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:03:58', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '333b153e-dae5-4136-b975-23c6472909aa' User entered '05 Aug 2020 12:03'	System	05 Aug 2020 16:04:25
	System	05 Aug 2020 16:04:25

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 7'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:13', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '328893d1-24d9-46dc-9025-0e7bf7dacf09'	System	06 Aug 2020 16:42:29
User entered 'None (1)'	System	06 Aug 2020 16:42:29

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:21', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '328893d1-24d9-46dc-9025-0e7bf7dacf09'	System	06 Aug 2020 16:42:29
User entered 'No (N)'	System	06 Aug 2020 16:42:29

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:23', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '328893d1-24d9-46dc-9025-0e7bf7dacf09' User entered 'No (N)'	System	06 Aug 2020 16:42:29
	System	06 Aug 2020 16:42:29



US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:25', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '328893d1-24d9-46dc-9025-0e7bf7dacf09'	System	06 Aug 2020 16:42:29
User entered 'None (1)'	System	06 Aug 2020 16:42:29

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:27', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '328893d1-24d9-46dc-9025-0e7bf7dacf09' User entered '06 Aug 2020 12:42'	System	06 Aug 2020 16:42:29
	System	06 Aug 2020 16:42:29

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:04:26', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b39a4fc0-39d8-492b-8fc0-46a65893134d' User entered 'None (0)'	System	31 Jul 2020 20:04:51
	System	31 Jul 2020 20:04:51

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:04:29', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b39a4fc0-39d8-492b-8fc0-46a65893134d' User entered 'None (0)'	System	31 Jul 2020 20:04:51
	System	31 Jul 2020 20:04:51

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:04:31', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b39a4fc0-39d8-492b-8fc0-46a65893134d' User entered 'None (0)'	System	31 Jul 2020 20:04:51
	System	31 Jul 2020 20:04:51



US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:04:34', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b39a4fc0-39d8-492b-8fc0-46a65893134d' User entered 'None (0)'	System	31 Jul 2020 20:04:51
	System	31 Jul 2020 20:04:51

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:04:38', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b39a4fc0-39d8-492b-8fc0-46a65893134d' User entered 'None (0)'	System	31 Jul 2020 20:04:51
	System	31 Jul 2020 20:04:51

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:04:40', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b39a4fc0-39d8-492b-8fc0-46a65893134d' User entered 'None (0)'	System	31 Jul 2020 20:04:51
	System	31 Jul 2020 20:04:51

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:04:46', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b39a4fc0-39d8-492b-8fc0-46a65893134d' User entered 'No (N)'	System	31 Jul 2020 20:04:51
	System	31 Jul 2020 20:04:51

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T16:04:49', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b39a4fc0-39d8-492b-8fc0-46a65893134d' User entered '31 Jul 2020 16:04'	System	31 Jul 2020 20:04:51
	System	31 Jul 2020 20:04:51

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Jul 2020 15:51'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Jul 2020 18:21'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 19:47:32



US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:31', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4b8b5922-a2b7-4487-986f-52f5c3d978dd' User entered 'None (0)'	System	01 Aug 2020 03:01:58
	System	01 Aug 2020 03:01:58

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:36', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4b8b5922-a2b7-4487-986f-52f5c3d978dd'	System	01 Aug 2020 03:01:58
User entered 'No interference with activity (1)'	System	01 Aug 2020 03:01:58

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:39', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4b8b5922-a2b7-4487-986f-52f5c3d978dd' User entered 'None (0)'	System	01 Aug 2020 03:01:58
	System	01 Aug 2020 03:01:58

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:42', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4b8b5922-a2b7-4487-986f-52f5c3d978dd' User entered 'None (0)'	System	01 Aug 2020 03:01:58
	System	01 Aug 2020 03:01:58

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:44', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4b8b5922-a2b7-4487-986f-52f5c3d978dd' User entered 'None (0)'	System	01 Aug 2020 03:01:58
	System	01 Aug 2020 03:01:58

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:47', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4b8b5922-a2b7-4487-986f-52f5c3d978dd' User entered 'None (0)'	System	01 Aug 2020 03:01:58
	System	01 Aug 2020 03:01:58

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4b8b5922-a2b7-4487-986f-52f5c3d978dd' User entered 'No (N)'	System	01 Aug 2020 03:01:58
	System	01 Aug 2020 03:01:58

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-07-31T23:01:55', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4b8b5922-a2b7-4487-986f-52f5c3d978dd' User entered '31 Jul 2020 23:01'	System	01 Aug 2020 03:01:58
	System	01 Aug 2020 03:01:58



**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Jul 2020 19:16'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 2'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:48', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0a4ab0b4-77ef-4058-99bb-0087f65c109c' User entered 'None (0)'	System	01 Aug 2020 16:41:05
	System	01 Aug 2020 16:41:05

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:50', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0a4ab0b4-77ef-4058-99bb-0087f65c109c' User entered 'None (0)'	System	01 Aug 2020 16:41:05
	System	01 Aug 2020 16:41:05

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0a4ab0b4-77ef-4058-99bb-0087f65c109c' User entered 'None (0)'	System	01 Aug 2020 16:41:05
	System	01 Aug 2020 16:41:05

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:54', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0a4ab0b4-77ef-4058-99bb-0087f65c109c' User entered 'None (0)'	System	01 Aug 2020 16:41:05
	System	01 Aug 2020 16:41:05

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:56', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0a4ab0b4-77ef-4058-99bb-0087f65c109c' User entered 'None (0)'	System	01 Aug 2020 16:41:05
	System	01 Aug 2020 16:41:05



US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:40:58', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0a4ab0b4-77ef-4058-99bb-0087f65c109c' User entered 'None (0)'	System	01 Aug 2020 16:41:05
	System	01 Aug 2020 16:41:05

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:41:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0a4ab0b4-77ef-4058-99bb-0087f65c109c' User entered 'No (N)'	System	01 Aug 2020 16:41:05
	System	01 Aug 2020 16:41:05

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-01T12:41:03', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0a4ab0b4-77ef-4058-99bb-0087f65c109c' User entered '01 Aug 2020 12:41'	System	01 Aug 2020 16:41:05
	System	01 Aug 2020 16:41:05

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 3'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:55', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2aec46d9-7d58-48a6-b4f5-946c08d82aef'	System	02 Aug 2020 19:17:14
User entered 'No interference with activity (1)'	System	02 Aug 2020 19:17:14

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:16:59', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2aec46d9-7d58-48a6-b4f5-946c08d82aef'	System	02 Aug 2020 19:17:14
User entered 'No interference with activity (1)'	System	02 Aug 2020 19:17:14



US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:17:02', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2aec46d9-7d58-48a6-b4f5-946c08d82aef' User entered 'None (0)'	System	02 Aug 2020 19:17:14
	System	02 Aug 2020 19:17:14

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:17:05', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2aec46d9-7d58-48a6-b4f5-946c08d82aef' User entered 'None (0)'	System	02 Aug 2020 19:17:14
	System	02 Aug 2020 19:17:14

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:17:07', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2aec46d9-7d58-48a6-b4f5-946c08d82aef' User entered 'None (0)'	System	02 Aug 2020 19:17:14
	System	02 Aug 2020 19:17:14

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:17:09', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2aec46d9-7d58-48a6-b4f5-946c08d82aef' User entered 'None (0)'	System	02 Aug 2020 19:17:14
	System	02 Aug 2020 19:17:14

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:17:11', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2aec46d9-7d58-48a6-b4f5-946c08d82aef' User entered 'No (N)'	System	02 Aug 2020 19:17:14
	System	02 Aug 2020 19:17:14

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-02T15:17:13', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2aec46d9-7d58-48a6-b4f5-946c08d82aef' User entered '02 Aug 2020 15:17'	System	02 Aug 2020 19:17:14
	System	02 Aug 2020 19:17:14

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 19:47:32



US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 4'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:26', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '16ef30cd-61fe-40b2-8182-94064329e06b'	System	03 Aug 2020 16:07:50
User entered 'No interference with activity (1)'	System	03 Aug 2020 16:07:50

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:32', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '16ef30cd-61fe-40b2-8182-94064329e06b' User entered 'None (0)'	System	03 Aug 2020 16:07:50
	System	03 Aug 2020 16:07:50

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:34', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '16ef30cd-61fe-40b2-8182-94064329e06b' User entered 'None (0)'	System	03 Aug 2020 16:07:50
	System	03 Aug 2020 16:07:50

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:36', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '16ef30cd-61fe-40b2-8182-94064329e06b' User entered 'None (0)'	System	03 Aug 2020 16:07:50
	System	03 Aug 2020 16:07:50

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:39', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '16ef30cd-61fe-40b2-8182-94064329e06b' User entered 'None (0)'	System	03 Aug 2020 16:07:50
	System	03 Aug 2020 16:07:50

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:41', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '16ef30cd-61fe-40b2-8182-94064329e06b' User entered 'None (0)'	System	03 Aug 2020 16:07:50
	System	03 Aug 2020 16:07:50

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:44', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '16ef30cd-61fe-40b2-8182-94064329e06b' User entered 'No (N)'	System	03 Aug 2020 16:07:50
	System	03 Aug 2020 16:07:50



**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-03T12:07:46', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '16ef30cd-61fe-40b2-8182-94064329e06b' User entered '03 Aug 2020 12:07'	System	03 Aug 2020 16:07:50
	System	03 Aug 2020 16:07:50

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 5'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:15', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a86d1053-e10f-4ab3-a3b9-ef90d550992b' User entered 'None (0)'	System	05 Aug 2020 02:31:26
	System	05 Aug 2020 02:31:26

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a86d1053-e10f-4ab3-a3b9-ef90d550992b' User entered 'None (0)'	System	05 Aug 2020 02:31:26
	System	05 Aug 2020 02:31:26

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:17', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a86d1053-e10f-4ab3-a3b9-ef90d550992b' User entered 'None (0)'	System	05 Aug 2020 02:31:26
	System	05 Aug 2020 02:31:26

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:18', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a86d1053-e10f-4ab3-a3b9-ef90d550992b' User entered 'None (0)'	System	05 Aug 2020 02:31:26
	System	05 Aug 2020 02:31:26



US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:20', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a86d1053-e10f-4ab3-a3b9-ef90d550992b' User entered 'None (0)'	System	05 Aug 2020 02:31:26
	System	05 Aug 2020 02:31:26

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:21', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a86d1053-e10f-4ab3-a3b9-ef90d550992b' User entered 'None (0)'	System	05 Aug 2020 02:31:26
	System	05 Aug 2020 02:31:26

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:23', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a86d1053-e10f-4ab3-a3b9-ef90d550992b' User entered 'No (N)'	System	05 Aug 2020 02:31:26
	System	05 Aug 2020 02:31:26

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-04T22:31:25', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a86d1053-e10f-4ab3-a3b9-ef90d550992b' User entered '04 Aug 2020 22:31'	System	05 Aug 2020 02:31:26
	System	05 Aug 2020 02:31:26

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 6'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:04:01', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1b73b88-765f-48ef-8f63-0e637447b552'	System	05 Aug 2020 16:04:28
User entered 'None (0)'	System	05 Aug 2020 16:04:28



US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:04:02', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1b73b88-765f-48ef-8f63-0e637447b552'	System	05 Aug 2020 16:04:28
User entered 'None (0)'	System	05 Aug 2020 16:04:28

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:04:04', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1b73b88-765f-48ef-8f63-0e637447b552'	System	05 Aug 2020 16:04:28
User entered 'None (0)'	System	05 Aug 2020 16:04:28

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:04:06', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1b73b88-765f-48ef-8f63-0e637447b552'	System	05 Aug 2020 16:04:28
User entered 'None (0)'	System	05 Aug 2020 16:04:28

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:04:08', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1b73b88-765f-48ef-8f63-0e637447b552'	System	05 Aug 2020 16:04:28
User entered 'None (0)'	System	05 Aug 2020 16:04:28

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:04:09', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1b73b88-765f-48ef-8f63-0e637447b552'	System	05 Aug 2020 16:04:28
User entered 'None (0)'	System	05 Aug 2020 16:04:28

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:04:12', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1b73b88-765f-48ef-8f63-0e637447b552'	System	05 Aug 2020 16:04:28
User entered 'No (N)'	System	05 Aug 2020 16:04:28

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-05T12:04:14', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e1b73b88-765f-48ef-8f63-0e637447b552'	System	05 Aug 2020 16:04:28
User entered '05 Aug 2020 12:04'	System	05 Aug 2020 16:04:28

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 19:47:32



**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 7'	System	31 Jul 2020 19:47:32

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:30', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f998d185-2a97-4662-9c5f-67659af5691c' User entered 'None (0)'	System	06 Aug 2020 16:42:50
	System	06 Aug 2020 16:42:50

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:32', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f998d185-2a97-4662-9c5f-67659af5691c' User entered 'None (0)'	System	06 Aug 2020 16:42:50
	System	06 Aug 2020 16:42:50

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:34', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f998d185-2a97-4662-9c5f-67659af5691c' User entered 'None (0)'	System	06 Aug 2020 16:42:50
	System	06 Aug 2020 16:42:50

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:35', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f998d185-2a97-4662-9c5f-67659af5691c' User entered 'None (0)'	System	06 Aug 2020 16:42:50
	System	06 Aug 2020 16:42:50

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:37', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f998d185-2a97-4662-9c5f-67659af5691c' User entered 'None (0)'	System	06 Aug 2020 16:42:50
	System	06 Aug 2020 16:42:50

US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:38', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f998d185-2a97-4662-9c5f-67659af5691c' User entered 'None (0)'	System	06 Aug 2020 16:42:50
	System	06 Aug 2020 16:42:50



US3182114

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:46', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f998d185-2a97-4662-9c5f-67659af5691c' User entered 'No (N)'	System	06 Aug 2020 16:42:50
	System	06 Aug 2020 16:42:50

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-06T12:42:48', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f998d185-2a97-4662-9c5f-67659af5691c' User entered '06 Aug 2020 12:42'	System	06 Aug 2020 16:42:50
	System	06 Aug 2020 16:42:50

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 19:47:32

**US3182114**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Yes (Y)'	Cassie Uminski	12 Aug 2020 14:49:33

**US3182114**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered '07 Aug 2020'	Cassie Uminski (b) (4)	12 Aug 2020 14:49:33

US3182114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	12 Aug 2020 14:49:33

US3182114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	12 Aug 2020 14:49:33
	(b) (4)	



US3182114

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 14:49:38

**US3182114**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'I'	System	12 Aug 2020 14:49:38

**US3182114**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	17 Aug 2020 14:12:49

**US3182114**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered '14 Aug 2020'	Alec Ireland (b) (4)	17 Aug 2020 14:12:49

**US3182114**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4)	17 Aug 2020 14:12:49

US3182114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	17 Aug 2020 14:12:49

US3182114

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	17 Aug 2020 14:12:58

**US3182114**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'I'	System	17 Aug 2020 14:12:58



**US3182114**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	25 Aug 2020 18:55:17

**US3182114**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered '21 Aug 2020'	Alec Ireland (b) (4)	25 Aug 2020 18:55:17

**US3182114**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	25 Aug 2020 18:55:17

US3182114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	25 Aug 2020 18:55:17

**US3182114**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	25 Aug 2020 18:55:22

**US3182114**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'I'	System	25 Aug 2020 18:55:22

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	31 Aug 2020 18:28:10

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Aug 2020'	Amy Maroun (b) (4)	31 Aug 2020 18:28:10



**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Clinic (Clinic)'	Amy Maroun (b) (4)	31 Aug 2020 18:28:10

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'VISIT2'	System	31 Aug 2020 18:28:10

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20
	(b) (4)	

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Aug 2020'	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '13:30'	(b) (4)	01 Sep 2020 19:49:20
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '31 Aug 2020 13:30'	System	01 Sep 2020 19:49:20

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '98.5' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 19:49:20



**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	(b) (4)	01 Sep 2020 19:49:20
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '86'	(b) (4)	
	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20
	(b) (4)	

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'bpm'	System	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'breaths/min'	System	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '150'	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'mmHg'	System	01 Sep 2020 19:49:20



US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '92'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'mmHg'	System	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski	01 Sep 2020 19:49:20

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Aug 2020'	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '14:50'	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '31 Aug 2020 14:50'	System	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '98.6' F	(b) (4)	
	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20
	(b) (4)	



**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Oral (Oral)'	(b) (4)	
	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20
	(b) (4)	

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	(b) (4)	01 Sep 2020 19:49:20
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '69'	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'bpm'	System	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '16'	Cassie Uminski (b) (4)	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'breaths/min'	System	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '153'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'mmHg'	System	01 Sep 2020 19:49:20



US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User closed query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Oct 2020 10:44:44
Query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' answered with 'NCS per investigator' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	06 Oct 2020 19:12:28
User opened query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 04:15:23
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 04:15:07
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Subject did not take BP meds today.' (Site from System).	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 19:49:42
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Sep 2020 19:49:20
User entered '101'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 19:49:20

US3182114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'mmHg'	System	01 Sep 2020 19:49:20

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:03

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Aug 2020'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:03

US3182114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	31 Aug 2020 18:28:34

US3182114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	31 Aug 2020 18:28:34

US3182114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

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 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	31 Aug 2020 18:28:34

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:31:10**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 18:28:34



US3182114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Aug 2020'	Amy Maroun (b) (4)	31 Aug 2020 18:28:34

US3182114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '14:15' reason for change: Data Entry Error	(b) (4)	
	Amy Maroun (b) (4)	31 Aug 2020 18:46:22
User entered '11:15'	(b) (4)	
	Amy Maroun (b) (4)	31 Aug 2020 18:28:34
	(b) (4)	

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:31:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '31 Aug 2020 14:15'	System	31 Aug 2020 18:46:22
User entered '31 Aug 2020 11:15'	System	31 Aug 2020 18:28:34

US3182114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Left Arm (LEFT ARM)'	Amy Maroun (b) (4)	31 Aug 2020 18:28:34

US3182114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'ONCE'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:31:10**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 18:28:34

US3182114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:26

US3182114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Aug 2020'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:26



**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '13:58'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:26

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '31 Aug 2020 13:58'	System	01 Sep 2020 19:50:26

US3182114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:31:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '31 Aug 2020'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:15

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:15
	(b) (4)	

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:15

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '13:48'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:15

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '31 Aug 2020 13:48'	System	01 Sep 2020 19:50:15

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:15
	(b) (4)	



**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'No (N)'	Cassie Uminski	01 Sep 2020 19:50:15

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:31:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	Cassie Uminski (b) (4)	01 Sep 2020 19:50:15

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered empty.	System	01 Sep 2020 19:50:15

US3182114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Sep 2020 19:50:29

**US3182114**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'I'	System	01 Sep 2020 19:50:29

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:47:46', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '836bc853-b12f-49cf-bf5c-23ec7702d986' User entered 'Yes (Y)'	System	31 Aug 2020 18:48:18
	System	31 Aug 2020 18:48:18

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:48:05', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '836bc853-b12f-49cf-bf5c-23ec7702d986' User entered '98.4'	System	31 Aug 2020 18:48:18
	System	31 Aug 2020 18:48:18



US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:48:12', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '836bc853-b12f-49cf-bf5c-23ec7702d986'	System	31 Aug 2020 18:48:18
User entered 'No (N)'	System	31 Aug 2020 18:48:18

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:48:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '836bc853-b12f-49cf-bf5c-23ec7702d986'	System	31 Aug 2020 18:48:18
User entered '31 Aug 2020 14:48'	System	31 Aug 2020 18:48:18

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Aug 2020 14:35'	System	31 Aug 2020 18:46:22
User entered '31 Aug 2020 11:35'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Aug 2020 17:05'	System	31 Aug 2020 18:46:22
User entered '31 Aug 2020 14:05'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:25', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '6c68f748-680a-46ef-999c-268810e196cc' User entered 'Yes (Y)'	System	01 Sep 2020 14:47:42
	System	01 Sep 2020 14:47:42

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:31', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '6c68f748-680a-46ef-999c-268810e196cc' User entered '97.9'	System	01 Sep 2020 14:47:42
	System	01 Sep 2020 14:47:42

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:34', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '6c68f748-680a-46ef-999c-268810e196cc' User entered 'No (N)'	System	01 Sep 2020 14:47:42
	System	01 Sep 2020 14:47:42



**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:37', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '6c68f748-680a-46ef-999c-268810e196cc' User entered '01 Sep 2020 10:47'	System	01 Sep 2020 14:47:42
	System	01 Sep 2020 14:47:42

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Aug 2020 18:00'	System	31 Aug 2020 18:46:22
User entered '31 Aug 2020 15:00'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 2'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:04', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9e2eed3e-4e4b-43f2-8915-d62f2f4d7d87'	System	02 Sep 2020 04:03:19
User entered 'Yes (Y)'	System	02 Sep 2020 04:03:19

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:09', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9e2eed3e-4e4b-43f2-8915-d62f2f4d7d87' User entered '98.4'	System	02 Sep 2020 04:03:19
	System	02 Sep 2020 04:03:19

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:11', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9e2eed3e-4e4b-43f2-8915-d62f2f4d7d87'	System	02 Sep 2020 04:03:19
User entered 'No (N)'	System	02 Sep 2020 04:03:19

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:14', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9e2eed3e-4e4b-43f2-8915-d62f2f4d7d87' User entered '02 Sep 2020 00:03'	System	02 Sep 2020 04:03:19
	System	02 Sep 2020 04:03:19



**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 3'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:57:38', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4c2c9b40-f1ce-4b8b-93b6-f8629a906ab3' User entered 'Yes (Y)'	System	02 Sep 2020 16:57:49
	System	02 Sep 2020 16:57:49

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:57:41', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4c2c9b40-f1ce-4b8b-93b6-f8629a906ab3' User entered '97.6'	System	02 Sep 2020 16:57:49
	System	02 Sep 2020 16:57:49

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:57:43', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4c2c9b40-f1ce-4b8b-93b6-f8629a906ab3' User entered 'No (N)'	System	02 Sep 2020 16:57:49
	System	02 Sep 2020 16:57:49

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:57:46', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4c2c9b40-f1ce-4b8b-93b6-f8629a906ab3' User entered '02 Sep 2020 12:57'	System	02 Sep 2020 16:57:49
	System	02 Sep 2020 16:57:49

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:28:34



US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 4'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:06', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'd2cab1d2-0da1-42e7-8dd9-d632efde491a' User entered 'Yes (Y)'	System	03 Sep 2020 23:10:17
	System	03 Sep 2020 23:10:17

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:11', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'd2cab1d2-0da1-42e7-8dd9-d632efde491a' User entered '98.1'	System	03 Sep 2020 23:10:17
	System	03 Sep 2020 23:10:17

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:13', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'd2cab1d2-0da1-42e7-8dd9-d632efde491a' User entered 'No (N)'	System	03 Sep 2020 23:10:17
	System	03 Sep 2020 23:10:17

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:15', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'd2cab1d2-0da1-42e7-8dd9-d632efde491a' User entered '03 Sep 2020 19:10'	System	03 Sep 2020 23:10:17
	System	03 Sep 2020 23:10:17

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:28:34



US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 5'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:05:50', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2e15a039-95e8-4528-90f9-2183b769d5b7' User entered 'Yes (Y)'	System	04 Sep 2020 17:06:07
	System	04 Sep 2020 17:06:07

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:05:57', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2e15a039-95e8-4528-90f9-2183b769d5b7' User entered '98.1'	System	04 Sep 2020 17:06:07
	System	04 Sep 2020 17:06:07

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2e15a039-95e8-4528-90f9-2183b769d5b7'	System	04 Sep 2020 17:06:07
User entered 'No (N)'	System	04 Sep 2020 17:06:07

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:03', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2e15a039-95e8-4528-90f9-2183b769d5b7' User entered '04 Sep 2020 13:06'	System	04 Sep 2020 17:06:07
	System	04 Sep 2020 17:06:07

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 6'	System	31 Aug 2020 18:28:34



US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:00:54', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a3ee304f-6fd1-47ed-8a6d-13df527c23ef' User entered 'No (N)'	System	05 Sep 2020 16:01:29
	System	05 Sep 2020 16:01:29

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:00:56', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a3ee304f-6fd1-47ed-8a6d-13df527c23ef' User entered 'No (N)'	System	05 Sep 2020 16:01:29
	System	05 Sep 2020 16:01:29

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:00:59', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a3ee304f-6fd1-47ed-8a6d-13df527c23ef' User entered '05 Sep 2020 12:00'	System	05 Sep 2020 16:01:29
	System	05 Sep 2020 16:01:29

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 7'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:26:53', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'aa037778-3850-432b-9b3c-75ce0e49451f' User entered 'Yes (Y)'	System	06 Sep 2020 16:27:08
	System	06 Sep 2020 16:27:08

US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:26:58', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'aa037778-3850-432b-9b3c-75ce0e49451f' User entered '98.1'	System	06 Sep 2020 16:27:08
	System	06 Sep 2020 16:27:08



US3182114

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'aa037778-3850-432b-9b3c-75ce0e49451f' User entered 'No (N)'	System	06 Sep 2020 16:27:08
	System	06 Sep 2020 16:27:08

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:03', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'aa037778-3850-432b-9b3c-75ce0e49451f' User entered '06 Sep 2020 12:27'	System	06 Sep 2020 16:27:08
	System	06 Sep 2020 16:27:08

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:48:53', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9a4c92f5-3dc2-4814-ac9c-a38e5bc33d59'	System	31 Aug 2020 18:49:06
User entered 'None (1)'	System	31 Aug 2020 18:49:06

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:48:55', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9a4c92f5-3dc2-4814-ac9c-a38e5bc33d59' User entered 'No (N)'	System	31 Aug 2020 18:49:06
	System	31 Aug 2020 18:49:06

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:48:57', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9a4c92f5-3dc2-4814-ac9c-a38e5bc33d59' User entered 'No (N)'	System	31 Aug 2020 18:49:06
	System	31 Aug 2020 18:49:06



US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:49:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9a4c92f5-3dc2-4814-ac9c-a38e5bc33d59'	System	31 Aug 2020 18:49:06
User entered 'None (1)'	System	31 Aug 2020 18:49:06

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:49:04', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9a4c92f5-3dc2-4814-ac9c-a38e5bc33d59' User entered '31 Aug 2020 14:49'	System	31 Aug 2020 18:49:06
	System	31 Aug 2020 18:49:06

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Aug 2020 14:35'	System	31 Aug 2020 18:46:22
User entered '31 Aug 2020 11:35'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Aug 2020 17:05'	System	31 Aug 2020 18:46:22
User entered '31 Aug 2020 14:05'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:42', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c1fbf8b2-0cea-48cd-820c-aaba96f001f6'	System	01 Sep 2020 14:47:57
User entered 'None (1)'	System	01 Sep 2020 14:47:57

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:45', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c1fbf8b2-0cea-48cd-820c-aaba96f001f6'	System	01 Sep 2020 14:47:57
User entered 'No (N)'	System	01 Sep 2020 14:47:57

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:47', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c1fbf8b2-0cea-48cd-820c-aaba96f001f6' User entered 'No (N)'	System	01 Sep 2020 14:47:57
	System	01 Sep 2020 14:47:57



US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:48', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c1fbf8b2-0cea-48cd-820c-aaba96f001f6'	System	01 Sep 2020 14:47:57
User entered 'None (1)'	System	01 Sep 2020 14:47:57

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:51', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c1fbf8b2-0cea-48cd-820c-aaba96f001f6' User entered '01 Sep 2020 10:47'	System	01 Sep 2020 14:47:57
	System	01 Sep 2020 14:47:57

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Aug 2020 18:00'	System	31 Aug 2020 18:46:22
User entered '31 Aug 2020 15:00'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 2'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:17', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ed353d75-97ee-45ed-87ff-3d003be1eafe' User entered 'None (1)'	System	02 Sep 2020 04:03:29
	System	02 Sep 2020 04:03:29

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:19', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ed353d75-97ee-45ed-87ff-3d003be1eafe' User entered 'No (N)'	System	02 Sep 2020 04:03:29
	System	02 Sep 2020 04:03:29

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:22', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ed353d75-97ee-45ed-87ff-3d003be1eafe' User entered 'No (N)'	System	02 Sep 2020 04:03:29
	System	02 Sep 2020 04:03:29



US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:24', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ed353d75-97ee-45ed-87ff-3d003be1eafe' User entered 'None (1)'	System	02 Sep 2020 04:03:29
	System	02 Sep 2020 04:03:29

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:26', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ed353d75-97ee-45ed-87ff-3d003be1eafe' User entered '02 Sep 2020 00:03'	System	02 Sep 2020 04:03:29
	System	02 Sep 2020 04:03:29

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 3'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:57:55', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '87fbcffe-0c93-491e-add8-96a545a3b581' User entered 'None (1)'	System	02 Sep 2020 16:58:03
	System	02 Sep 2020 16:58:03

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:57:57', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '87fbcffe-0c93-491e-add8-96a545a3b581' User entered 'No (N)'	System	02 Sep 2020 16:58:03
	System	02 Sep 2020 16:58:03

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:57:58', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '87fbcffe-0c93-491e-add8-96a545a3b581' User entered 'No (N)'	System	02 Sep 2020 16:58:03
	System	02 Sep 2020 16:58:03



US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:57:59', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '87fbcffe-0c93-491e-add8-96a545a3b581'	System	02 Sep 2020 16:58:03
User entered 'None (1)'	System	02 Sep 2020 16:58:03

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:58:02', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '87fbcffe-0c93-491e-add8-96a545a3b581' User entered '02 Sep 2020 12:58'	System	02 Sep 2020 16:58:03
	System	02 Sep 2020 16:58:03

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 4'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:18', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '3e14c425-65a4-46e6-b3de-d0e618896d9c' User entered 'None (1)'	System	03 Sep 2020 23:10:28
	System	03 Sep 2020 23:10:28

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:20', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '3e14c425-65a4-46e6-b3de-d0e618896d9c' User entered 'No (N)'	System	03 Sep 2020 23:10:28
	System	03 Sep 2020 23:10:28

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:21', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '3e14c425-65a4-46e6-b3de-d0e618896d9c' User entered 'No (N)'	System	03 Sep 2020 23:10:28
	System	03 Sep 2020 23:10:28



US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:22', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '3e14c425-65a4-46e6-b3de-d0e618896d9c' User entered 'None (1)'	System	03 Sep 2020 23:10:28
	System	03 Sep 2020 23:10:28

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:24', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '3e14c425-65a4-46e6-b3de-d0e618896d9c' User entered '03 Sep 2020 19:10'	System	03 Sep 2020 23:10:28
	System	03 Sep 2020 23:10:28

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 5'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:06', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '49b2295f-5b74-4c41-8ec9-82b0ec442a28'	System	04 Sep 2020 17:06:18
User entered 'None (1)'	System	04 Sep 2020 17:06:18

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:08', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '49b2295f-5b74-4c41-8ec9-82b0ec442a28' User entered 'No (N)'	System	04 Sep 2020 17:06:18
	System	04 Sep 2020 17:06:18

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:09', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '49b2295f-5b74-4c41-8ec9-82b0ec442a28' User entered 'No (N)'	System	04 Sep 2020 17:06:18
	System	04 Sep 2020 17:06:18



US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:11', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '49b2295f-5b74-4c41-8ec9-82b0ec442a28'	System	04 Sep 2020 17:06:18
User entered 'None (1)'	System	04 Sep 2020 17:06:18

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:13', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '49b2295f-5b74-4c41-8ec9-82b0ec442a28' User entered '04 Sep 2020 13:06'	System	04 Sep 2020 17:06:18
	System	04 Sep 2020 17:06:18

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 6'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:02', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fd7ba60b-319b-4952-86f7-b65d6c7b0f4f' User entered 'None (1)'	System	05 Sep 2020 16:01:44
	System	05 Sep 2020 16:01:44

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:04', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fd7ba60b-319b-4952-86f7-b65d6c7b0f4f' User entered 'No (N)'	System	05 Sep 2020 16:01:44
	System	05 Sep 2020 16:01:44

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:05', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fd7ba60b-319b-4952-86f7-b65d6c7b0f4f' User entered 'No (N)'	System	05 Sep 2020 16:01:44
	System	05 Sep 2020 16:01:44



US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:07', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fd7ba60b-319b-4952-86f7-b65d6c7b0f4f' User entered 'None (1)'	System	05 Sep 2020 16:01:44
	System	05 Sep 2020 16:01:44

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:09', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fd7ba60b-319b-4952-86f7-b65d6c7b0f4f' User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:01:44
	System	05 Sep 2020 16:01:44

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 7'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:08', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f4047983-dd61-4d1b-b1e2-6f952396b493' User entered 'None (1)'	System	06 Sep 2020 16:27:22
	System	06 Sep 2020 16:27:22

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:13', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f4047983-dd61-4d1b-b1e2-6f952396b493' User entered 'No (N)'	System	06 Sep 2020 16:27:22
	System	06 Sep 2020 16:27:22

US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f4047983-dd61-4d1b-b1e2-6f952396b493' User entered 'No (N)'	System	06 Sep 2020 16:27:22
	System	06 Sep 2020 16:27:22



US3182114

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:17', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f4047983-dd61-4d1b-b1e2-6f952396b493'	System	06 Sep 2020 16:27:22
User entered 'None (1)'	System	06 Sep 2020 16:27:22

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:20', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'f4047983-dd61-4d1b-b1e2-6f952396b493' User entered '06 Sep 2020 12:27'	System	06 Sep 2020 16:27:22
	System	06 Sep 2020 16:27:22

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:49:10', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '19ffc3ee-d6f2-4545-a5db-2f65da97616f' User entered 'None (0)'	System	31 Aug 2020 18:49:30
	System	31 Aug 2020 18:49:30

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:49:12', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '19ffc3ee-d6f2-4545-a5db-2f65da97616f' User entered 'None (0)'	System	31 Aug 2020 18:49:30
	System	31 Aug 2020 18:49:30

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:49:14', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '19ffc3ee-d6f2-4545-a5db-2f65da97616f' User entered 'None (0)'	System	31 Aug 2020 18:49:30
	System	31 Aug 2020 18:49:30



US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:49:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '19ffc3ee-d6f2-4545-a5db-2f65da97616f' User entered 'None (0)'	System	31 Aug 2020 18:49:30
	System	31 Aug 2020 18:49:30

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:49:18', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '19ffc3ee-d6f2-4545-a5db-2f65da97616f' User entered 'None (0)'	System	31 Aug 2020 18:49:30
	System	31 Aug 2020 18:49:30

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:49:21', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '19ffc3ee-d6f2-4545-a5db-2f65da97616f' User entered 'None (0)'	System	31 Aug 2020 18:49:30
	System	31 Aug 2020 18:49:30

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:49:24', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '19ffc3ee-d6f2-4545-a5db-2f65da97616f' User entered 'No (N)'	System	31 Aug 2020 18:49:30
	System	31 Aug 2020 18:49:30

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-08-31T14:49:27', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '19ffc3ee-d6f2-4545-a5db-2f65da97616f' User entered '31 Aug 2020 14:49'	System	31 Aug 2020 18:49:30
	System	31 Aug 2020 18:49:30

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Aug 2020 14:35'	System	31 Aug 2020 18:46:22
User entered '31 Aug 2020 11:35'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:31:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Aug 2020 17:05'	System	31 Aug 2020 18:46:22
User entered '31 Aug 2020 14:05'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:28:34



US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:54', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '93c61553-814a-410c-b1e2-26ca0cb98242' User entered 'None (0)'	System	01 Sep 2020 14:48:10
	System	01 Sep 2020 14:48:10

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:55', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '93c61553-814a-410c-b1e2-26ca0cb98242' User entered 'None (0)'	System	01 Sep 2020 14:48:10
	System	01 Sep 2020 14:48:10

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:57', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '93c61553-814a-410c-b1e2-26ca0cb98242' User entered 'None (0)'	System	01 Sep 2020 14:48:10
	System	01 Sep 2020 14:48:10

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:47:59', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '93c61553-814a-410c-b1e2-26ca0cb98242' User entered 'None (0)'	System	01 Sep 2020 14:48:10
	System	01 Sep 2020 14:48:10

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:48:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '93c61553-814a-410c-b1e2-26ca0cb98242' User entered 'None (0)'	System	01 Sep 2020 14:48:10
	System	01 Sep 2020 14:48:10

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:48:02', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '93c61553-814a-410c-b1e2-26ca0cb98242' User entered 'None (0)'	System	01 Sep 2020 14:48:10
	System	01 Sep 2020 14:48:10

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:48:04', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '93c61553-814a-410c-b1e2-26ca0cb98242' User entered 'No (N)'	System	01 Sep 2020 14:48:10
	System	01 Sep 2020 14:48:10

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-01T10:48:07', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '93c61553-814a-410c-b1e2-26ca0cb98242'	System	01 Sep 2020 14:48:10
User entered '01 Sep 2020 10:48'	System	01 Sep 2020 14:48:10



US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:31:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '31 Aug 2020 18:00'	System	31 Aug 2020 18:46:22
User entered '31 Aug 2020 15:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 2'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:30', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8cbc0ca3-e65f-4ec1-9f35-8c7d7fd84edc' User entered 'None (0)'	System	02 Sep 2020 04:03:44
	System	02 Sep 2020 04:03:44

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:31', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8cbc0ca3-e65f-4ec1-9f35-8c7d7fd84edc' User entered 'None (0)'	System	02 Sep 2020 04:03:44
	System	02 Sep 2020 04:03:44

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:33', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8cbc0ca3-e65f-4ec1-9f35-8c7d7fd84edc' User entered 'None (0)'	System	02 Sep 2020 04:03:44
	System	02 Sep 2020 04:03:44

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:34', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8cbc0ca3-e65f-4ec1-9f35-8c7d7fd84edc' User entered 'None (0)'	System	02 Sep 2020 04:03:44
	System	02 Sep 2020 04:03:44

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:36', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8cbc0ca3-e65f-4ec1-9f35-8c7d7fd84edc' User entered 'None (0)'	System	02 Sep 2020 04:03:44
	System	02 Sep 2020 04:03:44



**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:37', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8cbc0ca3-e65f-4ec1-9f35-8c7d7fd84edc' User entered 'None (0)'	System	02 Sep 2020 04:03:44
	System	02 Sep 2020 04:03:44

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:39', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8cbc0ca3-e65f-4ec1-9f35-8c7d7fd84edc'	System	02 Sep 2020 04:03:44
User entered 'No (N)'	System	02 Sep 2020 04:03:44

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T00:03:41', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '8cbc0ca3-e65f-4ec1-9f35-8c7d7fd84edc' User entered '02 Sep 2020 00:03'	System	02 Sep 2020 04:03:44
	System	02 Sep 2020 04:03:44

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 3'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:58:06', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b84579b0-5469-42c3-b866-127632cc1b94' User entered 'None (0)'	System	02 Sep 2020 16:58:20
	System	02 Sep 2020 16:58:20

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:58:07', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b84579b0-5469-42c3-b866-127632cc1b94'	System	02 Sep 2020 16:58:20
User entered 'None (0)'	System	02 Sep 2020 16:58:20



US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:58:08', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b84579b0-5469-42c3-b866-127632cc1b94' User entered 'None (0)'	System	02 Sep 2020 16:58:20
	System	02 Sep 2020 16:58:20

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:58:10', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b84579b0-5469-42c3-b866-127632cc1b94' User entered 'None (0)'	System	02 Sep 2020 16:58:20
	System	02 Sep 2020 16:58:20

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:58:11', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b84579b0-5469-42c3-b866-127632cc1b94' User entered 'None (0)'	System	02 Sep 2020 16:58:20
	System	02 Sep 2020 16:58:20

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:58:13', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b84579b0-5469-42c3-b866-127632cc1b94' User entered 'None (0)'	System	02 Sep 2020 16:58:20
	System	02 Sep 2020 16:58:20

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:58:14', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b84579b0-5469-42c3-b866-127632cc1b94'	System	02 Sep 2020 16:58:20
User entered 'No (N)'	System	02 Sep 2020 16:58:20

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-02T12:58:18', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b84579b0-5469-42c3-b866-127632cc1b94' User entered '02 Sep 2020 12:58'	System	02 Sep 2020 16:58:20
	System	02 Sep 2020 16:58:20

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:28:34



US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 4'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:28', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '060ea400-ce32-46f3-8c1e-cc15aaba4bd5' User entered 'None (0)'	System	03 Sep 2020 23:10:42
	System	03 Sep 2020 23:10:42

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:29', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '060ea400-ce32-46f3-8c1e-cc15aaba4bd5' User entered 'None (0)'	System	03 Sep 2020 23:10:42
	System	03 Sep 2020 23:10:42

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:30', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '060ea400-ce32-46f3-8c1e-cc15aaba4bd5' User entered 'None (0)'	System	03 Sep 2020 23:10:42
	System	03 Sep 2020 23:10:42

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:32', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '060ea400-ce32-46f3-8c1e-cc15aaba4bd5' User entered 'None (0)'	System	03 Sep 2020 23:10:42
	System	03 Sep 2020 23:10:42

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:33', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '060ea400-ce32-46f3-8c1e-cc15aaba4bd5' User entered 'None (0)'	System	03 Sep 2020 23:10:42
	System	03 Sep 2020 23:10:42

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:35', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '060ea400-ce32-46f3-8c1e-cc15aaba4bd5' User entered 'None (0)'	System	03 Sep 2020 23:10:42
	System	03 Sep 2020 23:10:42

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:37', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '060ea400-ce32-46f3-8c1e-cc15aaba4bd5' User entered 'No (N)'	System	03 Sep 2020 23:10:42
	System	03 Sep 2020 23:10:42



**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-03T19:10:39', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '060ea400-ce32-46f3-8c1e-cc15aaba4bd5' User entered '03 Sep 2020 19:10'	System	03 Sep 2020 23:10:42
	System	03 Sep 2020 23:10:42

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 5'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cc274ec5-0f94-4a2d-b199-93cafc1ea102' User entered 'None (0)'	System	04 Sep 2020 17:06:29
	System	04 Sep 2020 17:06:29

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:17', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cc274ec5-0f94-4a2d-b199-93cafc1ea102' User entered 'None (0)'	System	04 Sep 2020 17:06:29
	System	04 Sep 2020 17:06:29

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:18', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cc274ec5-0f94-4a2d-b199-93cafc1ea102' User entered 'None (0)'	System	04 Sep 2020 17:06:29
	System	04 Sep 2020 17:06:29

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:19', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cc274ec5-0f94-4a2d-b199-93cafc1ea102' User entered 'None (0)'	System	04 Sep 2020 17:06:29
	System	04 Sep 2020 17:06:29



US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:20', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cc274ec5-0f94-4a2d-b199-93cafc1ea102' User entered 'None (0)'	System	04 Sep 2020 17:06:29
	System	04 Sep 2020 17:06:29

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:22', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cc274ec5-0f94-4a2d-b199-93cafc1ea102' User entered 'None (0)'	System	04 Sep 2020 17:06:29
	System	04 Sep 2020 17:06:29

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:24', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cc274ec5-0f94-4a2d-b199-93cafc1ea102'	System	04 Sep 2020 17:06:29
User entered 'No (N)'	System	04 Sep 2020 17:06:29

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-04T13:06:26', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cc274ec5-0f94-4a2d-b199-93cafc1ea102'	System	04 Sep 2020 17:06:29
User entered '04 Sep 2020 13:06'	System	04 Sep 2020 17:06:29

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 6'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:12', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fec6e537-1d2b-4364-a99d-ccf3a797a1d8' User entered 'None (0)'	System	05 Sep 2020 16:02:07
	System	05 Sep 2020 16:02:07



US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:13', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fec6e537-1d2b-4364-a99d-ccf3a797a1d8' User entered 'None (0)'	System	05 Sep 2020 16:02:07
	System	05 Sep 2020 16:02:07

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:15', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fec6e537-1d2b-4364-a99d-ccf3a797a1d8' User entered 'None (0)'	System	05 Sep 2020 16:02:07
	System	05 Sep 2020 16:02:07

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fec6e537-1d2b-4364-a99d-ccf3a797a1d8' User entered 'None (0)'	System	05 Sep 2020 16:02:07
	System	05 Sep 2020 16:02:07

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:17', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fec6e537-1d2b-4364-a99d-ccf3a797a1d8' User entered 'None (0)'	System	05 Sep 2020 16:02:07
	System	05 Sep 2020 16:02:07

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:19', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fec6e537-1d2b-4364-a99d-ccf3a797a1d8' User entered 'None (0)'	System	05 Sep 2020 16:02:07
	System	05 Sep 2020 16:02:07

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:20', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fec6e537-1d2b-4364-a99d-ccf3a797a1d8'	System	05 Sep 2020 16:02:07
User entered 'No (N)'	System	05 Sep 2020 16:02:07

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-05T12:01:22', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fec6e537-1d2b-4364-a99d-ccf3a797a1d8' User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:02:07
	System	05 Sep 2020 16:02:07

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:28:34



**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Aug 2020 18:28:34
User entered 'Day 7'	System	31 Aug 2020 18:28:34

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:23', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a7ca2353-2638-4ae9-972e-120fcacad296' User entered 'None (0)'	System	06 Sep 2020 16:27:39
	System	06 Sep 2020 16:27:39

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:24', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a7ca2353-2638-4ae9-972e-120fcacad296' User entered 'None (0)'	System	06 Sep 2020 16:27:39
	System	06 Sep 2020 16:27:39

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:25', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a7ca2353-2638-4ae9-972e-120fcacad296' User entered 'None (0)'	System	06 Sep 2020 16:27:39
	System	06 Sep 2020 16:27:39

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:27', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a7ca2353-2638-4ae9-972e-120fcacad296' User entered 'None (0)'	System	06 Sep 2020 16:27:39
	System	06 Sep 2020 16:27:39

US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:28', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a7ca2353-2638-4ae9-972e-120fcacad296' User entered 'None (0)'	System	06 Sep 2020 16:27:39
	System	06 Sep 2020 16:27:39

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:30', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a7ca2353-2638-4ae9-972e-120fcacad296' User entered 'None (0)'	System	06 Sep 2020 16:27:39
	System	06 Sep 2020 16:27:39



US3182114

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:32', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a7ca2353-2638-4ae9-972e-120fcacad296'	System	06 Sep 2020 16:27:39
User entered 'No (N)'	System	06 Sep 2020 16:27:39

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-06T12:27:35', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'a7ca2353-2638-4ae9-972e-120fcacad296' User entered '06 Sep 2020 12:27'	System	06 Sep 2020 16:27:39
	System	06 Sep 2020 16:27:39

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:31:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:28:34

**US3182114**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:52:33

**US3182114**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered '8 Sep 2020'	Alec Ireland (b) (4)	09 Sep 2020 17:52:33

US3182114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:52:33

US3182114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:52:33



US3182114

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:08:57
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	09 Sep 2020 17:52:38

**US3182114**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'I'	System	09 Sep 2020 17:52:38

**US3182114**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:45:42

**US3182114**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '15 Sep 2020'	Alec Ireland (b) (4)	15 Sep 2020 18:45:42

**US3182114**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:45:42

US3182114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:45:42

**US3182114**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 18:45:35
	Alec Ireland (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'I'	System	15 Sep 2020 18:45:35



**US3182114**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:55:44

US3182114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:35:07
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date correct as is.' (Site from System).	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:55:48
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Sep 2020 16:55:44
User entered '20 Sep 2020'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:55:44

**US3182114**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:55:44

**US3182114**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:55:44

**US3182114**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 16:55:52

**US3182114**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'I'	System	24 Sep 2020 16:55:52

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered 'Yes (Y)'	Cassie Uminski	01 Oct 2020 18:31:00

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered '28 Sep 2020'	Cassie Uminski (b) (4)	01 Oct 2020 18:31:00



**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered 'Clinic (Clinic)'	Cassie Uminski	01 Oct 2020 18:31:00

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'VISIT3'	System	01 Oct 2020 18:31:00

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Oct 2020 18:31:14

US3182114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered '28 Sep 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Oct 2020 18:31:14

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered '14:15'	Cassie Uminski (b) (4)	01 Oct 2020 18:31:14

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '28 Sep 2020 14:15'	System	01 Oct 2020 18:31:14

US3182114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered '99.5' F	Cassie Uminski (b) (4)	01 Oct 2020 18:31:14

US3182114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	01 Oct 2020 18:31:14



**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered empty.	Cassie Uminski (b) (4)	01 Oct 2020 18:31:14

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered '76'	Cassie Uminski (b) (4)	01 Oct 2020 18:31:14

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'bpm'	System	01 Oct 2020 18:31:14

US3182114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Oct 2020 18:31:14

US3182114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'breaths/min'	System	01 Oct 2020 18:31:14

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered '116'	Cassie Uminski (b) (4)	01 Oct 2020 18:31:14

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'mmHg'	System	01 Oct 2020 18:31:14

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:23
User entered '85'	Cassie Uminski (b) (4)	01 Oct 2020 18:31:14



US3182114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'mmHg'	System	01 Oct 2020 18:31:14

US3182114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01

US3182114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'No (N)'	Cassie Uminski	01 Oct 2020 18:31:22

US3182114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered empty.	Cassie Uminski (b) (4)	01 Oct 2020 18:31:22

US3182114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski	01 Oct 2020 18:31:30

US3182114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '28 Sep 2020'	Cassie Uminski (b) (4)	01 Oct 2020 18:31:30

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered '14:29'	Cassie Uminski (b) (4)	01 Oct 2020 18:31:30



**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered '28 Sep 2020 14:29'	System	01 Oct 2020 18:31:30

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:09:16
User entered 'Yes (Y)'	Cassie Uminski	01 Oct 2020 18:31:38

**US3182114**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'I'	System	01 Oct 2020 18:31:38

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 64'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-30T00:01:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cafff1fb-35b5-4156-8fbe-aa39bb925949' User entered 'No (N)'	System	30 Sep 2020 04:01:31

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

Have you been exposed to someone with 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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-30T00:01:25', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cafff1fb-35b5-4156-8fbe-aa39bb925949'	System	30 Sep 2020 04:01:31
User entered 'No (N)'	System	30 Sep 2020 04:01:31

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-09-30T00:01:29', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'cafff1fb-35b5-4156-8fbe-aa39bb925949' User entered '30 Sep 2020 00:01:29'	System	30 Sep 2020 04:01:31
	System	30 Sep 2020 04:01:31

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 19:47:32



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 71'	System	31 Jul 2020 19:47:32

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

[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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-10-07T02:08:50', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '567429ae-6390-4f1a-9161-237c9319abfb' User entered 'No (N)'	System	07 Oct 2020 06:08:58
	System	07 Oct 2020 06:08:58

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

Have you been exposed to someone with 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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-10-07T02:08:53', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '567429ae-6390-4f1a-9161-237c9319abfb' User entered 'No (N)'	System	07 Oct 2020 06:08:58
	System	07 Oct 2020 06:08:58

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-10-07T02:08:57', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '567429ae-6390-4f1a-9161-237c9319abfb' User entered '07 Oct 2020 02:08:57'	System	07 Oct 2020 06:08:58
	System	07 Oct 2020 06:08:58

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '07 Oct 2020 00:01'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '11 Oct 2020 23:59'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 78'	System	31 Jul 2020 19:47:32



US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

[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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-10-14T00:02:01', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4cd068ac-c081-4866-98b7-a421a2fc028e' User entered 'No (N)'	System	14 Oct 2020 04:02:15
	System	14 Oct 2020 04:02:15

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

Have you been exposed to someone with 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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-10-14T00:02:06', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4cd068ac-c081-4866-98b7-a421a2fc028e' User entered 'No (N)'	System	14 Oct 2020 04:02:15
	System	14 Oct 2020 04:02:15

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-10-14T00:02:10', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4cd068ac-c081-4866-98b7-a421a2fc028e' User entered '14 Oct 2020 00:02:10'	System	14 Oct 2020 04:02:15
	System	14 Oct 2020 04:02:15

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 92'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-10-28T00:01:36', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '71da6ec7-5d53-43f9-8b0e-8e6213a0b415'	System	28 Oct 2020 04:01:49
User entered 'No (N)'	System	28 Oct 2020 04:01:49

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-10-28T00:01:39', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '71da6ec7-5d53-43f9-8b0e-8e6213a0b415'	System	28 Oct 2020 04:01:49
User entered 'No (N)'	System	28 Oct 2020 04:01:49



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-10-28T00:01:44', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '71da6ec7-5d53-43f9-8b0e-8e6213a0b415' User entered '28 Oct 2020 00:01:44'	System	28 Oct 2020 04:01:49
	System	28 Oct 2020 04:01:49

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 99'	System	31 Jul 2020 19:47:32

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

[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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-04T00:01:26', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'd1fe6667-b662-493e-a0f1-4c757eb53958'	System	04 Nov 2020 05:01:38
User entered 'No (N)'	System	04 Nov 2020 05:01:38

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

Have you been exposed to someone with 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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-04T00:01:29', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'd1fe6667-b662-493e-a0f1-4c757eb53958'	System	04 Nov 2020 05:01:38
User entered 'No (N)'	System	04 Nov 2020 05:01:38

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-04T00:01:33', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'd1fe6667-b662-493e-a0f1-4c757eb53958' User entered '04 Nov 2020 00:01:33'	System	04 Nov 2020 05:01:38
	System	04 Nov 2020 05:01:38

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 19:47:32



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 106'	System	31 Jul 2020 19:47:32

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-11T00:01:17', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2708b54e-40f2-4241-8b8e-d70b997948b3' User entered 'No (N)'	System	11 Nov 2020 05:01:38
	System	11 Nov 2020 05:01:38

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-11T00:01:20', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2708b54e-40f2-4241-8b8e-d70b997948b3'	System	11 Nov 2020 05:01:38
User entered 'No (N)'	System	11 Nov 2020 05:01:38

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-11T00:01:23', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2708b54e-40f2-4241-8b8e-d70b997948b3' User entered '11 Nov 2020 00:01:23'	System	11 Nov 2020 05:01:38
	System	11 Nov 2020 05:01:38

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered 'Day 113'	System	31 Jul 2020 19:47:32



US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:25', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered 'Yes (Y)'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:30', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e'	System	18 Nov 2020 05:02:24
User entered 'No (N)'	System	18 Nov 2020 05:02:24

US3182114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:10

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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:35', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered 'Yes (Y)'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '0'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '1'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '1'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '0'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '0'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '0'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '1'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '1'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '1'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '0'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '0'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '1'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '1'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '1'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '0'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '0'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '0'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Please 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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:02:04', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e'	System	18 Nov 2020 05:02:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:02:10', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered 'No (N)'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-18T00:02:15', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '418c7c7a-c1c3-4dc1-8a92-d34392333f9e' User entered '18 Nov 2020 00:02:15'	System	18 Nov 2020 05:02:24
	System	18 Nov 2020 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '18 Nov 2020 00:01'	System	31 Jul 2020 19:47:32



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:58:51
Data entry locked.	System	31 Jul 2020 19:47:32
User entered '22 Nov 2020 23:59'	System	31 Jul 2020 19:47:32

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-19T08:24:35', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '56529849-a04a-404e-8a74-bc1375b3e16b'	System	19 Nov 2020 13:24:45
User entered 'No (N)'	System	19 Nov 2020 13:24:45

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-19T08:24:39', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '56529849-a04a-404e-8a74-bc1375b3e16b'	System	19 Nov 2020 13:24:45
User entered 'No (N)'	System	19 Nov 2020 13:24:45

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-19T08:24:42', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '56529849-a04a-404e-8a74-bc1375b3e16b' User entered '19 Nov 2020 08:24:42'	System	19 Nov 2020 13:24:45
	System	19 Nov 2020 13:24:45

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-22T00:10:02', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ff440d2d-a0ed-413a-8fb3-20e486ade19d'	System	22 Nov 2020 05:18:44
User entered 'No (N)'	System	22 Nov 2020 05:18:44

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-22T00:10:05', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ff440d2d-a0ed-413a-8fb3-20e486ade19d' User entered 'No (N)'	System	22 Nov 2020 05:18:44

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-22T00:10:08', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ff440d2d-a0ed-413a-8fb3-20e486ade19d' User entered '22 Nov 2020 00:10:08'	System	22 Nov 2020 05:18:44
	System	22 Nov 2020 05:18:44

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-29T00:01:14', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '3a06ca0e-468f-4564-9aaa-c184891ccf90'	System	29 Nov 2020 05:01:31
User entered 'No (N)'	System	29 Nov 2020 05:01:31

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-29T00:01:17', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '3a06ca0e-468f-4564-9aaa-c184891ccf90'	System	29 Nov 2020 05:01:31
User entered 'No (N)'	System	29 Nov 2020 05:01:31



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-11-29T00:01:20', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '3a06ca0e-468f-4564-9aaa-c184891ccf90' User entered '29 Nov 2020 00:01:20'	System	29 Nov 2020 05:01:31
	System	29 Nov 2020 05:01:31

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-06T00:01:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c1b2f720-a713-4cd5-8023-83b48bee5a4c'	System	06 Dec 2020 05:01:36
User entered 'No (N)'	System	06 Dec 2020 05:01:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-06T00:01:19', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c1b2f720-a713-4cd5-8023-83b48bee5a4c'	System	06 Dec 2020 05:01:36
User entered 'No (N)'	System	06 Dec 2020 05:01:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-06T00:01:22', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c1b2f720-a713-4cd5-8023-83b48bee5a4c' User entered '06 Dec 2020 00:01:22'	System	06 Dec 2020 05:01:36
	System	06 Dec 2020 05:01:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-15T12:02:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e02c0c89-a0e5-47fa-a1c1-cb7dfb1140af' User entered 'No (N)'	System	15 Dec 2020 17:02:23
	System	15 Dec 2020 17:02:23

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-15T12:02:17', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e02c0c89-a0e5-47fa-a1c1-cb7dfb1140af' User entered 'No (N)'	System	15 Dec 2020 17:02:23

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-15T12:02:21', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e02c0c89-a0e5-47fa-a1c1-cb7dfb1140af' User entered '15 Dec 2020 12:02:21'	System	15 Dec 2020 17:02:23
	System	15 Dec 2020 17:02:23

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-22T12:01:18', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4be2c396-3550-4737-8edf-67f0277884fa' User entered 'No (N)'	System	22 Dec 2020 17:01:55
	System	22 Dec 2020 17:01:55

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-22T12:01:24', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4be2c396-3550-4737-8edf-67f0277884fa' User entered 'Yes (Y)'	System	22 Dec 2020 17:01:55
	System	22 Dec 2020 17:01:55

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Please 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-22T12:01:36', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4be2c396-3550-4737-8edf-67f0277884fa'	System	22 Dec 2020 17:01:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Dec 2020 17:01:55

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-22T12:01:39', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '4be2c396-3550-4737-8edf-67f0277884fa' User entered '22 Dec 2020 12:01:39'	System	22 Dec 2020 17:01:55
	System	22 Dec 2020 17:01:55

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-29T12:00:37', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0b8c2003-5253-4ae2-a9ef-f4064351f7ae' User entered 'No (N)'	System	29 Dec 2020 18:00:45
	System	29 Dec 2020 18:00:45



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-29T12:00:39', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0b8c2003-5253-4ae2-a9ef-f4064351f7ae'	System	29 Dec 2020 18:00:45
User entered 'No (N)'	System	29 Dec 2020 18:00:45

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2020-12-29T12:00:42', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0b8c2003-5253-4ae2-a9ef-f4064351f7ae' User entered '29 Dec 2020 12:00:42'	System	29 Dec 2020 18:00:45
	System	29 Dec 2020 18:00:45

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-03T00:01:34', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'bb4ce5b5-20e7-49eb-978a-3bb6a47ccaf8'	System	03 Jan 2021 05:02:24
User entered 'No (N)'	System	03 Jan 2021 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-03T00:01:40', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'bb4ce5b5-20e7-49eb-978a-3bb6a47ccaf8'	System	03 Jan 2021 05:02:24
User entered 'No (N)'	System	03 Jan 2021 05:02:24

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-03T00:01:46', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'bb4ce5b5-20e7-49eb-978a-3bb6a47ccaf8' User entered '03 Jan 2021 00:01:46'	System	03 Jan 2021 05:02:24
	System	03 Jan 2021 05:02:24



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-10T00:01:40', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'aec158eb-9cd7-435f-af00-6e13c55770a3'	System	10 Jan 2021 05:03:22
User entered 'No (N)'	System	10 Jan 2021 05:03:22

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-10T00:02:17', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'aec158eb-9cd7-435f-af00-6e13c55770a3'	System	10 Jan 2021 05:03:22
User entered 'No (N)'	System	10 Jan 2021 05:03:22

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-10T00:02:19', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'aec158eb-9cd7-435f-af00-6e13c55770a3' User entered '10 Jan 2021 00:02:19'	System	10 Jan 2021 05:03:22
	System	10 Jan 2021 05:03:22

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-17T00:01:36', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fca02bbf-50b5-4ade-bf1c-452a74431297'	System	17 Jan 2021 05:01:58
User entered 'No (N)'	System	17 Jan 2021 05:01:58

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-17T00:01:38', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fca02bbf-50b5-4ade-bf1c-452a74431297'	System	17 Jan 2021 05:01:58
User entered 'No (N)'	System	17 Jan 2021 05:01:58

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-17T00:01:40', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'fca02bbf-50b5-4ade-bf1c-452a74431297' User entered '17 Jan 2021 00:01:40'	System	17 Jan 2021 05:01:58
	System	17 Jan 2021 05:01:58

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-24T00:01:35', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b97a2731-21ed-4d25-a1e6-230c619be08e' User entered 'No (N)'	System	24 Jan 2021 05:02:22
	System	24 Jan 2021 05:02:22



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-24T00:01:41', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b97a2731-21ed-4d25-a1e6-230c619be08e'	System	24 Jan 2021 05:02:22
User entered 'No (N)'	System	24 Jan 2021 05:02:22

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-24T00:01:49', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b97a2731-21ed-4d25-a1e6-230c619be08e' User entered '24 Jan 2021 00:01:49'	System	24 Jan 2021 05:02:22

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-31T08:07:14', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b2b297dd-34cb-4935-b961-8f24ad85980b'	System	31 Jan 2021 13:07:21
User entered 'No (N)'	System	31 Jan 2021 13:07:21

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-31T08:07:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b2b297dd-34cb-4935-b961-8f24ad85980b'	System	31 Jan 2021 13:07:21
User entered 'No (N)'	System	31 Jan 2021 13:07:21

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-01-31T08:07:19', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'b2b297dd-34cb-4935-b961-8f24ad85980b' User entered '31 Jan 2021 08:07:19'	System	31 Jan 2021 13:07:21
	System	31 Jan 2021 13:07:21



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-07T12:57:12', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '1a80746c-51e4-4495-ad85-6f19eb2a48df' User entered 'No (N)'	System	07 Feb 2021 17:57:27
	System	07 Feb 2021 17:57:27

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-07T12:57:13', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '1a80746c-51e4-4495-ad85-6f19eb2a48df' User entered 'No (N)'	System	07 Feb 2021 17:57:27
	System	07 Feb 2021 17:57:27

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-07T12:57:16', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '1a80746c-51e4-4495-ad85-6f19eb2a48df' User entered '07 Feb 2021 12:57:16'	System	07 Feb 2021 17:57:27
	System	07 Feb 2021 17:57:27

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-14T00:04:21', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0fd01b9d-c7e3-42d7-9a8a-315ecfc0b0d6' User entered 'No (N)'	System	14 Feb 2021 05:04:46
	System	14 Feb 2021 05:04:46

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-14T00:04:23', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0fd01b9d-c7e3-42d7-9a8a-315ecfc0b0d6'	System	14 Feb 2021 05:04:46
User entered 'No (N)'	System	14 Feb 2021 05:04:46

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-14T00:04:28', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '0fd01b9d-c7e3-42d7-9a8a-315ecfc0b0d6' User entered '14 Feb 2021 00:04:28'	System	14 Feb 2021 05:04:46
	System	14 Feb 2021 05:04:46

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-21T00:19:26', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '359cdee6-1f71-409c-8bdc-08e26464b3ff' User entered 'No (N)'	System	21 Feb 2021 05:19:35
	System	21 Feb 2021 05:19:35



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-21T00:19:30', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '359cdee6-1f71-409c-8bdc-08e26464b3ff' User entered 'No (N)'	System	21 Feb 2021 05:19:35
	System	21 Feb 2021 05:19:35

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-21T00:19:33', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '359cdee6-1f71-409c-8bdc-08e26464b3ff' User entered '21 Feb 2021 00:19:33'	System	21 Feb 2021 05:19:35
	System	21 Feb 2021 05:19:35

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-28T00:01:23-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e7a93042-c265-477b-b4ac-067d5442483c' User entered 'No (N)'	System	28 Feb 2021 05:02:28
	System	28 Feb 2021 05:02:28

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-28T00:01:25-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e7a93042-c265-477b-b4ac-067d5442483c' User entered 'No (N)'	System	28 Feb 2021 05:02:28

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-28T00:01:29-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'e7a93042-c265-477b-b4ac-067d5442483c' User entered '28 Feb 2021 05:01:29'	System	28 Feb 2021 05:02:28
	System	28 Feb 2021 05:02:28



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-07T00:02:28-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9f469a63-944f-404f-b72b-b49f017fe147'	System	07 Mar 2021 05:04:26
User entered 'No (N)'	System	07 Mar 2021 05:04:26

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-07T00:02:31-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9f469a63-944f-404f-b72b-b49f017fe147'	System	07 Mar 2021 05:04:26
User entered 'No (N)'	System	07 Mar 2021 05:04:26

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-07T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '9f469a63-944f-404f-b72b-b49f017fe147' User entered '07 Mar 2021 00:02:34'	System	07 Mar 2021 05:04:26
	System	07 Mar 2021 05:04:26

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-14T00:02:31-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '02a8bf7f-c8d2-41e5-86f1-8425b814e563'	System	14 Mar 2021 05:06:30
User entered 'No (N)'	System	14 Mar 2021 05:06:30

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-14T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '02a8bf7f-c8d2-41e5-86f1-8425b814e563'	System	14 Mar 2021 05:06:30
User entered 'No (N)'	System	14 Mar 2021 05:06:30

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-14T00:02:37-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '02a8bf7f-c8d2-41e5-86f1-8425b814e563' User entered '14 Mar 2021 00:02:37'	System	14 Mar 2021 05:06:30
	System	14 Mar 2021 05:06:30

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-21T00:24:35-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '5b5c67a1-bf0f-4e3e-9d6d-4b2f7ed728c8'	System	21 Mar 2021 04:25:17
User entered 'Yes (Y)'	System	21 Mar 2021 04:25:17



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-21T00:24:38-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '5b5c67a1-bf0f-4e3e-9d6d-4b2f7ed728c8'	System	21 Mar 2021 04:25:17
User entered 'No (N)'	System	21 Mar 2021 04:25:17

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-21T00:24:45-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '5b5c67a1-bf0f-4e3e-9d6d-4b2f7ed728c8'	System	21 Mar 2021 04:25:17
User entered 'No (N)'	System	21 Mar 2021 04:25:17

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-21T00:24:57-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '5b5c67a1-bf0f-4e3e-9d6d-4b2f7ed728c8'	System	21 Mar 2021 04:25:17
User entered 'Yes (Y)'	System	21 Mar 2021 04:25:17

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Please 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-21T00:25:02-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '5b5c67a1-bf0f-4e3e-9d6d-4b2f7ed728c8'	System	21 Mar 2021 04:25:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Mar 2021 04:25:17

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-21T00:25:07-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '5b5c67a1-bf0f-4e3e-9d6d-4b2f7ed728c8'	System	21 Mar 2021 04:25:17
User entered '21 Mar 2021 00:25:07'	System	21 Mar 2021 04:25:17

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-28T21:25:58-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '966b172a-65d0-42d8-83c5-4124438d7f59'	System	30 Mar 2021 00:32:33
User entered 'No (N)'	System	30 Mar 2021 00:32:33

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-28T21:26:03-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '966b172a-65d0-42d8-83c5-4124438d7f59'	System	30 Mar 2021 00:32:33
User entered 'No (N)'	System	30 Mar 2021 00:32:33

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-03-28T21:26:05-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '966b172a-65d0-42d8-83c5-4124438d7f59'	System	30 Mar 2021 00:32:33
User entered '28 Mar 2021 21:26:05'	System	30 Mar 2021 00:32:33

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:26-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered 'Yes (Y)'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:29-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered 'No (N)'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:36-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered 'Yes (Y)'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe'	System	07 Apr 2021 01:39:16
User entered '1'	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe'	System	07 Apr 2021 01:39:16
User entered '1'	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '0'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '0'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '0'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe'	System	07 Apr 2021 01:39:16
User entered '1'	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe'	System	07 Apr 2021 01:39:16
User entered '1'	System	07 Apr 2021 01:39:16



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe'	System	07 Apr 2021 01:39:16
User entered '1'	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe'	System	07 Apr 2021 01:39:16
User entered '1'	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '0'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '0'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '0'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '0'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '0'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '0'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '0'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:49-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe'	System	07 Apr 2021 01:39:16
User entered '1'	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Please 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:52-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe'	System	07 Apr 2021 01:39:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:38:56-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe'	System	07 Apr 2021 01:39:16
User entered 'Yes (Y)'	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Please 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:39:00-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe'	System	07 Apr 2021 01:39:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-06T21:39:03-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '2423557f-ee3a-44c5-89ed-4f7a8ad16cbe' User entered '06 Apr 2021 21:39:03'	System	07 Apr 2021 01:39:16
	System	07 Apr 2021 01:39:16

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-11T00:02:14-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ec4f3b05-5ebf-4518-9b7c-8d76f75b7e82'	System	11 Apr 2021 04:03:11
User entered 'No (N)'	System	11 Apr 2021 04:03:11

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-11T00:02:15-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ec4f3b05-5ebf-4518-9b7c-8d76f75b7e82'	System	11 Apr 2021 04:03:11
User entered 'No (N)'	System	11 Apr 2021 04:03:11

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-11T00:02:18-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'ec4f3b05-5ebf-4518-9b7c-8d76f75b7e82'	System	11 Apr 2021 04:03:11
User entered '11 Apr 2021 00:02:18'	System	11 Apr 2021 04:03:11

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-18T01:40:20-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c62b9d96-7a0c-44ef-b9bc-16806ff9ff6c'	System	18 Apr 2021 05:40:27
User entered 'No (N)'	System	18 Apr 2021 05:40:27



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-18T01:40:23-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c62b9d96-7a0c-44ef-b9bc-16806ff9ff6c'	System	18 Apr 2021 05:40:27
User entered 'No (N)'	System	18 Apr 2021 05:40:27

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-18T01:40:25-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'c62b9d96-7a0c-44ef-b9bc-16806ff9ff6c'	System	18 Apr 2021 05:40:27
User entered '18 Apr 2021 01:40:25'	System	18 Apr 2021 05:40:27

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-26T22:34:31-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'bc853c59-8615-43bc-9e1b-29c1ed75328e' User entered 'No (N)'	System	27 Apr 2021 02:34:37
	System	27 Apr 2021 02:34:37

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-26T22:34:32-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'bc853c59-8615-43bc-9e1b-29c1ed75328e' User entered 'No (N)'	System	27 Apr 2021 02:34:37
	System	27 Apr 2021 02:34:37

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-04-26T22:34:35-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: 'bc853c59-8615-43bc-9e1b-29c1ed75328e' User entered '26 Apr 2021 22:34:35'	System	27 Apr 2021 02:34:37
	System	27 Apr 2021 02:34:37



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-05-02T00:02:26-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '51d4e018-596d-4157-8396-5e08374cb0e3'	System	02 May 2021 04:03:59
User entered 'No (N)'	System	02 May 2021 04:03:59

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Have you been exposed to someone with 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 (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-05-02T00:02:27-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '51d4e018-596d-4157-8396-5e08374cb0e3'	System	02 May 2021 04:03:59
User entered 'No (N)'	System	02 May 2021 04:03:59

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-05-02T00:02:31-04:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '51d4e018-596d-4157-8396-5e08374cb0e3'	System	02 May 2021 04:03:59
User entered '02 May 2021 00:02:31'	System	02 May 2021 04:03:59

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:05:36



**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 11:05:36



**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 11:05:36

**US3182114**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:31:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:05:36
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 11:05:36

US3182114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:31:10

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 03:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-28T00:01:35-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '7c2e7300-4c69-4e2b-974b-ead930c38c66'	System	28 Feb 2021 05:02:51
User entered 'No (N)'	System	28 Feb 2021 05:02:51

**US3182114**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 03:49:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5112592-D8DE-46EF-A5CF-55DEA3BBFFAF)', Time: '2021-02-28T00:01:40-05:00', User OID: 'PatientReportedOutcome (US3182114)', ODM File OID: '7c2e7300-4c69-4e2b-974b-ead930c38c66' User entered '28 Feb 2021 05:01:40'	System	28 Feb 2021 05:02:51
	System	28 Feb 2021 05:02:51



**US3182114**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski	29 Oct 2020 14:50:09

**US3182114**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '26 Oct 2020'	Cassie Uminski	29 Oct 2020 14:50:09

**US3182114**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	29 Oct 2020 14:50:09

**US3182114**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	29 Oct 2020 14:50:09
	(b) (4)	

**US3182114**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski	29 Oct 2020 14:50:44

**US3182114**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:38:01
User entered 'I'	System	29 Oct 2020 14:50:44

**US3182114**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski	10 Dec 2020 02:32:04

**US3182114**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '01 Dec 2020'	Cassie Uminski (b) (4)	10 Dec 2020 02:32:04



**US3182114**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	10 Dec 2020 02:32:04

**US3182114**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	10 Dec 2020 02:32:04
	(b) (4)	

**US3182114**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Dec 2020 02:32:10

**US3182114**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered 'I'	System	10 Dec 2020 02:32:10

**US3182114**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	06 Jan 2021 14:38:23

**US3182114**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '29 Dec 2020'	Gabby Jacobs (b) (4)	06 Jan 2021 14:38:23

**US3182114**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	06 Jan 2021 14:38:23

US3182114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4) Gabby Jacobs (b) (4) (b) (4)	06 Jan 2021 14:38:23



**US3182114**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	06 Jan 2021 14:38:09

**US3182114**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered 'I'	System	06 Jan 2021 14:38:09

**US3182114**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Jan 2021 14:01:12

**US3182114**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '25 Jan 2021'	Cassie Uminski (b) (4)	28 Jan 2021 14:01:12

**US3182114**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	28 Jan 2021 14:01:12

**US3182114**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	28 Jan 2021 14:01:12
	(b) (4)	

**US3182114**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Jan 2021 14:01:27

**US3182114**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered 'I'	System	28 Jan 2021 14:01:27



**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:39:33

US3182114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User closed query 'Per GCL Lab Recon: Immuno : Sample dated "23` FEB 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in the Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' (Site from DM).		30 Mar 2021 14:47:47
Query 'Per GCL Lab Recon: Immuno : Sample dated "23` FEB 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in the Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	28 Mar 2021 04:01:19
User opened query 'Per GCL Lab Recon: Immuno : Sample dated "23` FEB 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in the Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 12:03:21
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:18:48
User entered '23 Feb 2021'	Cassie Uminski (b) (4) (b) (4)	27 Feb 2021 05:39:33

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	27 Feb 2021 05:39:33

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered 'VISIT4'	System	27 Feb 2021 05:39:33

US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Mar 2021 04:01:05

US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	28 Mar 2021 04:01:05

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '13:36'	Cassie Uminski (b) (4)	28 Mar 2021 04:01:05

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered '23 Feb 2021 13:36'	System	28 Mar 2021 04:01:05



US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '97.8' F	Cassie Uminski (b) (4)	28 Mar 2021 04:01:05

US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	28 Mar 2021 04:01:05

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered empty.	Cassie Uminski (b) (4)	28 Mar 2021 04:01:05

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '91'	Cassie Uminski (b) (4)	28 Mar 2021 04:01:05

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered 'bpm'	System	28 Mar 2021 04:01:05

US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '16'	Cassie Uminski (b) (4)	28 Mar 2021 04:01:05

US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered 'breaths/min'	System	28 Mar 2021 04:01:05

US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '147'	Cassie Uminski (b) (4)	28 Mar 2021 04:01:05



**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered 'mmHg'	System	28 Mar 2021 04:01:05

US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '84'	Cassie Uminski (b) (4)	28 Mar 2021 04:01:05

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered 'mmHg'	System	28 Mar 2021 04:01:05

US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31

US3182114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:39:40

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	27 Feb 2021 05:39:40

US3182114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Mar 2021 18:35:23



US3182114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	17 Mar 2021 18:35:23

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '14:05'	Cassie Uminski (b) (4)	17 Mar 2021 18:35:23

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered '23 Feb 2021 14:05'	System	17 Mar 2021 18:35:23

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	27 Feb 2021 05:39:47

**US3182114**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:55:31
User entered 'I'	System	27 Feb 2021 05:39:47

**US3182114**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:18
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:44:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Apr 2021 14:18:36

**US3182114**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:18
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:44:39
User entered '29 Mar 2021'	Cassie Uminski (b) (4)	07 Apr 2021 14:18:36

**US3182114**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:18
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:44:39
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	07 Apr 2021 14:18:36



US3182114

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:18
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:44:39
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	07 Apr 2021 14:18:36
	(b) (4)	

**US3182114**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:18
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:44:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Apr 2021 14:18:39

**US3182114**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:18
User entered 'I'	System	07 Apr 2021 14:18:39

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:31:10

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18NOV2020 is reported under Illness Visit Day 1 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)	02 Feb 2021 07:57:20
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18NOV2020 is reported under Illness Visit Day 1 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 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:19:36
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:25:39
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 18NOV2020 is reported under Illness Visit Day 1 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).		26 Nov 2020 08:47:35
User entered '18 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:42:07

**US3182114**

**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:31:10**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:39
User entered '09:30'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:42:07

**US3182114**

**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:31:10**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '18 Nov 2020 09:30'	System	20 Nov 2020 16:42:07

**US3182114**

**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:31:10**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:39
User entered 'Safety Call (Safety Call)'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:42:07

**US3182114**

**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:31:10**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:42:07



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 1 (Day 1)'	(b) (4)	
	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36
	(b) (4)	

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '19 Nov 2020'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '95'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

**US3182114**

**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 15:31:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98.8' F	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Moderate (Moderate)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Moderate (Moderate)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:27:36

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 2 (Day 2)'	(b) (4)	
	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54
	(b) (4)	

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '20 Nov 2020'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '89'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98.7' F	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:30:54



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Moderate (Moderate)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:30:54

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 3 (Day 3)'	(b) (4)	
	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '21 Nov 2020'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '100'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:32:11



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98.2' F	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:32:11



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:32:11

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:32:11

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 4 (Day 4)'	(b) (4)	
	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '22 Nov 2020'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '97'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	01 Dec 2020 17:33:37

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98.0' F	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:33:37



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 5 (Day 5)'	(b) (4)	
	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '23 Nov 2020'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '99'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	01 Dec 2020 17:34:40

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98.0' F	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:34:40



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Dec 2020 17:34:40

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	09 Dec 2020 01:48:48
User entered empty.	(b) (4) Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '24 Nov 2020'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '95'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98.1' F	(b) (4) Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:45:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 01:45:07

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	09 Dec 2020 01:49:18
User entered empty.	(b) (4) Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '25 Nov 2020'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '97'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98.0' F	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13



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**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 01:47:13

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	09 Dec 2020 01:49:34
User entered empty.	(b) (4) Jennifer Gaston (b) (4)	02 Dec 2020 11:20:45
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:20
User entered '26 Nov 2020'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:22
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:25
User entered '97'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:27
User entered '98.1' F	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:32
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:37
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:39
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:45
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:47
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:49
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:52
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:54
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:34:58
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:35:00
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:35:01
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:35:03
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:35:05
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:35:06
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:35:08
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:35:10
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:20:45



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	09 Dec 2020 01:49:49
User entered empty.	(b) (4) Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '27 Nov 2020'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98.0' F	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:17



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Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:22:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	09 Dec 2020 01:50:06
User entered empty.	(b) (4) Jennifer Gaston (b) (4)	02 Dec 2020 11:22:58
	(b) (4)	

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Form: Symptom Log (10)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:35
User entered '28 Nov 2020'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58



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Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:37
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:39
User entered '98'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	02 Dec 2020 11:22:58

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:43
User entered '97.8' F	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:46
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:47
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:49
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:51
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:52
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:55
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:57
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:39:59
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:40:00
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:40:02
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:40:04
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:40:07
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:40:08
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:40:12
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:40:13
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:40:15
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:22:58

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	09 Dec 2020 01:50:25
User entered empty.	(b) (4) Jennifer Gaston (b) (4)	02 Dec 2020 11:24:06
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:40:55
User entered '29 Nov 2020'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:40:57
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:00
User entered '96'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:01
User entered '98.0' F	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:07
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:09
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:13
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:15
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:17
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:19
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:20
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:22
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:24
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:25
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:27
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:28
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:31
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:33
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:34
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:41:36
User entered 'None (None)'	Jennifer Gaston (b) (4) (b) (4)	02 Dec 2020 11:24:06

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	09 Dec 2020 01:50:48
User entered empty.	(b) (4) Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '30 Nov 2020'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	02 Dec 2020 11:25:44

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '97.9' F	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

**US3182114**

**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 09 Jun 2021 15:31:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Jennifer Gaston (b) (4)	02 Dec 2020 11:25:44



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 16 (Day 16)' reason for change:	(b) (4)	
Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 13 (Day 13)'	(b) (4)	
	Cassie Uminski (b) (4)	09 Dec 2020 01:51:56
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:14
User entered '01 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:16
User entered '0'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:35
User entered '97'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	09 Dec 2020 01:51:56

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:36
User entered '97.8' F	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:39
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:40
User entered 'Mild (Mild)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:43
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:45
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:48
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:50
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:51
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:53
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:42:58
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:43:00
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:43:02
User entered 'Mild (Mild)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:43:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:43:08
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:43:11
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:43:12
User entered 'Mild (Mild)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:43:14
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:51:56

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 17 (Day 17)' reason for change:	(b) (4)	
Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 16:03:31
User entered 'Day 14 (Day 14)'	(b) (4)	
	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '02 Dec 2020'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '95'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	09 Dec 2020 01:52:55

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98.1' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:52:55

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:52:55

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:52:55



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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:52:55

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:52:55

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:52:55

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:52:55

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:52:55

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	09 Dec 2020 01:52:55

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 16:02:13
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	09 Dec 2020 01:55:17
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User closed query 'Please add in symptom logs for 16-17Nov and renumber days as needed. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:07:15
Query 'Please add in symptom logs for 16-17Nov and renumber days as needed. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:57
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:50
User opened query 'Please add in symptom logs for 16-17Nov and renumber days as needed. ' (Site from CRA).		08 Jan 2021 19:28:33
User entered '18 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:48
User entered '0'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:06:42
User closed query 'This is noted as 99% on the vital sign page. Should this be reported here? ' (Site from CRA).		01 Feb 2021 17:06:39
Query 'This is noted as 99% on the vital sign page. Should this be reported here? ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:05:44
User entered '99' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:05:39
User opened query 'This is noted as 99% on the vital sign page. Should this be reported here? ' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 19:27:06
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	09 Dec 2020 01:55:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User closed query "This is 97.9 on the vital sign page. Should this be reported here?" (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 17:06:48
DataPoint Verified.		01 Feb 2021 17:06:45
Query "This is 97.9 on the vital sign page. Should this be reported here?" answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	01 Feb 2021 16:05:47
User entered '97.9' F reason for change: Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 16:05:39
User opened query "This is 97.9 on the vital sign page. Should this be reported here?" (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 19:27:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:55
User entered 'Mild (Mild)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:59
User entered 'Mild (Mild)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:06
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:10
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:13
User entered 'Mild (Mild)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:19
User entered 'Mild (Mild)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:21
User entered 'Mild (Mild)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:25
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:32
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:34
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:46
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:49
User entered 'Mild (Mild)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:52
User entered 'Mild (Mild)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:57
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:00
User entered 'None (None)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:39
User entered 'Moderate (Moderate)'	Cassie Uminski (b) (4) (b) (4)	09 Dec 2020 01:55:17

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 1 (Day 1)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '16 Nov 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51



**US3182114**

**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 15:31:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Moderate (Moderate)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Moderate (Moderate)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 15:31:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Moderate (Moderate)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:01:51



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Day 2 (Day 2)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '17 Dec 2020'	Cassie Uminski (b) (4)	01 Feb 2021 16:04:33

**US3182114**

**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 09 Jun 2021 15:31:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Cassie Uminski (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '%'	System	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	Cassie Uminski (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Moderate (Moderate)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Moderate (Moderate)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Mild (Mild)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	Cassie Uminski (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'None (None)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:31:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Moderate (Moderate)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:04:33

**US3182114**

**Folder: Covid-19 Assessment 18 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 15:31:10**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '18 Nov 2020'	Cassie Uminski (b) (4)	30 Jan 2021 02:31:08

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:31:10

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	30 Jan 2021 02:31:08



US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:31:10

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'No (N)'	Cassie Uminski (b) (4)	30 Jan 2021 02:31:08

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Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:31:10

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '18 Nov 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	30 Jan 2021 02:31:08

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:31:10

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassie Uminski (b) (4)	30 Jan 2021 02:31:08

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:31:10

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	30 Jan 2021 02:31:08
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:31:10

[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)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'No (N)'	Cassie Uminski (b) (4)	30 Jan 2021 02:31:08

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:31:10

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	30 Jan 2021 02:31:08

US3182114

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:31:10

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	30 Jan 2021 02:31:08
	Cassie Uminski (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:31:10

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User entered '0'	System	30 Jan 2021 02:31:08



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Folder: Covid-19 Assessment 18 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:31:10

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:15
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:42:14

**US3182114**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Naqib Ahmad (b) (4) (b) (4)	08 Dec 2020 18:38:41

US3182114

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:31:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:02:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 18:02:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Jan 2021 18:02:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:38:41
User entered empty.	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:31:10

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
	(b) (4)	
User entered '20 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Jan 2021 18:02:59
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated "26NOV2020" is reported under Illness Visits 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.	(b) (4), (b) (6)	08 Jan 2021 07:21:08
' canceled (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated "26NOV2020" is reported under Illness Visits 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.	(b) (4), (b) (6)	11 Dec 2020 03:49:14
' (Site from DM).		
User entered empty.	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:31:10

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F616812078 is reported with 20NOV2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:04:34
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F616812078 is reported with 20NOV2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'DCF will be submitted to correct date. Correct as is in EDC' (Site from DM).	Cassie Uminski (b) (4)	09 Mar 2021 16:39:53
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F616812078 is reported with 20NOV2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 12:07:22
User accepted default value 'Day 5 (Day 5)'	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41

US3182114

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:31:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:02:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 18:02:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Jan 2021 18:02:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:38:41
User entered empty.	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:31:10

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
User closed query 'Please clarify date as this is day 3. Day 5 should be 22Nov2020. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:08:12
Query 'Please clarify date as this is day 3. Day 5 should be 22Nov2020. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:06:40
User entered '22 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:06:34
User opened query 'Please clarify date as this is day 3. Day 5 should be 22Nov2020. ' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 19:48:35
User entered '20 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:02:59
User entered empty.	Naqib Ahmad (b) (4) (b) (4)	08 Dec 2020 18:38:41

**US3182114**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Naqib Ahmad (b) (4) (b) (4)	08 Dec 2020 18:38:41



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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:31:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:02:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 18:02:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Jan 2021 18:02:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:38:41
User entered empty.	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

**US3182114**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
	(b) (4)	
User entered '24 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Jan 2021 18:02:59
	(b) (4)	
User entered empty.	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Naqib Ahmad (b) (4) (b) (4)	08 Dec 2020 18:38:41

US3182114

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:31:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 19:38:16
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:02:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 18:02:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Jan 2021 18:02:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:38:41
User entered empty.	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 19:38:18
User entered '26 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Jan 2021 18:02:59
User entered empty.	(b) (4)	
	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Naqib Ahmad (b) (4) (b) (4)	08 Dec 2020 18:38:41

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 19:49:28
User entered 'Yes (Y)'	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

US3182114

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:31:10

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
User closed query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 20NOV2020 sample as Illness Visit Day 5, however in EDC, Day 14 is on 20NOV2020 and DAY 5 is not collected. Please review the PPD portal and confirm the correct date and correct label for each sample and if there is a mismatch update the EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 09:07:42
Query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 20NOV2020 sample as Illness Visit Day 5, however in EDC, Day 14 is on 20NOV2020 and DAY 5 is not collected. Please review the PPD portal and confirm the correct date and correct label for each sample and if there is a mismatch update the EDC or PPD portal as appropriate. Thank you.' answered with 'DCF will be submitted as applicable.' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:09:05
User entered '02 Dec 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 18:02:59
User opened query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 20NOV2020 sample as Illness Visit Day 5, however in EDC, Day 14 is on 20NOV2020 and DAY 5 is not collected. Please review the PPD portal and confirm the correct date and correct label for each sample and if there is a mismatch update the EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 07:18:31
User entered '20 Nov 2020'	Naqib Ahmad (b) (4) (b) (4)	08 Dec 2020 18:38:41



**US3182114**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Naqib Ahmad (b) (4) (b) (4)	08 Dec 2020 18:38:41

US3182114

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:31:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 18:02:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 18:02:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Jan 2021 18:02:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:38:41
User entered empty.	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

US3182114

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:31:10

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
	(b) (4)	
User entered '08 Dec 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	08 Jan 2021 18:02:59
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated "02DEC2020" is reported under Illness Visits 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.	(b) (4), (b) (6)	08 Jan 2021 07:21:22
' canceled (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated "02DEC2020" is reported under Illness Visits 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.	(b) (4), (b) (6)	11 Dec 2020 03:49:32
' (Site from DM).		
User entered empty.	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

**US3182114**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Naqib Ahmad (b) (4) (b) (4)	08 Dec 2020 18:38:41

US3182114

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:31:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 16:09:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 16:09:50
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	01 Feb 2021 16:09:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:38:41
User entered empty.	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

**US3182114**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:38
	(b) (4)	
User entered empty.	Naqib Ahmad (b) (4)	08 Dec 2020 18:38:41
	(b) (4)	

US3182114

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User closed query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24NOV2020, 26NOV2020, 02DEC2020 and 08DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 09:08:01
Query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24NOV2020, 26NOV2020, 02DEC2020 and 08DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:12:11
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:22:38
User opened query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24NOV2020, 26NOV2020, 02DEC2020 and 08DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' (Site from DM).		08 Jan 2021 07:19:53
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is reported under Illness visits 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.	(b) (4), (b) (6)	08 Jan 2021 07:19:48
' canceled (Site from DM).		
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20NOV2020 is reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 03:47:51

US3182114

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is reported under Illness visits 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)	04 Dec 2020 03:03:57
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20NOV2020 is reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 00:33:20
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:43:14



**US3182114**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:22:40
User entered '18 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:43:14

US3182114

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:22:42
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:43:14

**US3182114**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User entered 'SICKD1'	System	20 Nov 2020 16:43:14

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:10

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered '18 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:10

**US3182114**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered '15:06'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:10

**US3182114**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User entered '18 Nov 2020 15:06'	System	20 Nov 2020 16:44:10

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered '175.3' cm	Cassie Uminski (b) (4)	20 Nov 2020 16:44:10
DataPoint set to visible.	(b) (4) System	20 Nov 2020 16:43:14



US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered '102.06' kg	Cassie Uminski (b) (4)	20 Nov 2020 16:44:10
DataPoint set to visible.	(b) (4) System	20 Nov 2020 16:43:14

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered '97.9' F	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:10

**US3182114**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:10

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered empty.	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:10

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered '84'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:10

**US3182114**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User entered 'bpm'	System	20 Nov 2020 16:44:10

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered '16'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:10

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User entered 'breaths/min'	System	20 Nov 2020 16:44:10



US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:10

**US3182114**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User entered 'mmHg'	System	20 Nov 2020 16:44:10

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:23:55
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:10

**US3182114**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User entered 'mmHg'	System	20 Nov 2020 16:44:10

US3182114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39

**US3182114**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39

**US3182114**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:25

US3182114

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:45
User entered '18 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:44:25



US3182114

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:31:10

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:55
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:45:10

US3182114

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:31:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:44:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:55
User entered '18 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	20 Nov 2020 16:45:10

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Feb 2021 15:56:18

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '27 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:56:18

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	01 Feb 2021 15:56:18

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 15:56:18

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:31:10**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '27 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:56:31

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:31:10**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:49
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 16:39:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:13:03



**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:31:10**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:56:31

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:31:10**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:45:49
User entered 'Amendment 6 or later (Amendment 6 or later)'	Cassie Uminski (b) (4)	09 Mar 2021 16:39:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:13:03

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:10

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '27 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:56:31

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:10

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4)	01 Feb 2021 15:56:31

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:31:10**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4)	01 Feb 2021 15:56:31

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:31:10**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Placebo (Placebo)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:56:31

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:31:10**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:56:31

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:31:10**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '1'	System	01 Feb 2021 15:56:31



**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'I'	System	01 Feb 2021 15:56:31

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '176.0' cm	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '108.4' kg	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '34.99483'	System	01 Feb 2021 15:58:28
DataPoint set to visible.	System	01 Feb 2021 15:56:31

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '176.0' cm	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '108.4' kg	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '34.99483'	System	01 Feb 2021 15:58:28
DataPoint set to visible.	System	01 Feb 2021 15:56:31

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	01 Feb 2021 15:58:28
	(b) (4)	



US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '27 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '15:03'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '27 Jan 2021 15:03'	System	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '97.8' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	01 Feb 2021 15:58:28
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '74'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28



**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'bpm'	System	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '15'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'breaths/min'	System	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '124'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mmHg'	System	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '85'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mmHg'	System	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '176.0' cm	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28



US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '108.4' kg	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '34.99483'	System	01 Feb 2021 15:58:28
DataPoint set to visible.	System	01 Feb 2021 15:56:31

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '27 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '15:40'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '27 Jan 2021 15:40'	System	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '98.4' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28



US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	01 Feb 2021 15:58:28
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '63'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'bpm'	System	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '14'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'breaths/min'	System	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '129'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mmHg'	System	01 Feb 2021 15:58:28



US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '77'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:58:28

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mmHg'	System	01 Feb 2021 15:58:28

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Feb 2021 15:59:26

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '27 Jan 2021'	Cassie Uminski (b) (4)	01 Feb 2021 15:59:26

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:59:46

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	01 Feb 2021 15:59:46
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	01 Feb 2021 15:59:46
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:31:10**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mRNA-1273'	System	01 Feb 2021 15:59:46
DataPoint set to visible.	System	01 Feb 2021 15:56:31



US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '27 Jan 2021'	Cassie Uminski (b) (4)	01 Feb 2021 15:59:46

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '15:10'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:59:46

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:31:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '27 Jan 2021 15:10'	System	01 Feb 2021 15:59:46

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Left Arm (LEFT ARM)'	Cassie Uminski (b) (4)	01 Feb 2021 15:59:46

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:31:10**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'ONCE'	System	01 Feb 2021 15:59:46

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 15:59:46

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Feb 2021 15:57:30

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '27 Jan 2021'	Cassie Uminski (b) (4)	01 Feb 2021 15:57:30



**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '15:00'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:57:30

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '27 Jan 2021 15:00'	System	01 Feb 2021 15:57:30

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:31:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Feb 2021 15:56:44

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:31:10**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '27 Jan 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:56:44

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:31:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '14:46'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:56:44

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:31:10**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '27 Jan 2021 14:46'	System	01 Feb 2021 15:56:44

US3182114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 15:59:52

**US3182114**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'I'	System	01 Feb 2021 15:59:52



**US3182114**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Feb 2021 20:00:49

**US3182114**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '03 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 20:00:49

**US3182114**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 20:00:49

**US3182114**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	Cassie Uminski (b) (4)	10 Feb 2021 20:00:49

**US3182114**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Feb 2021 20:00:58

**US3182114**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'I'	System	10 Feb 2021 20:00:58

**US3182114**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '1'	System	10 Feb 2021 20:00:58
DataPoint set to visible.	System	10 Feb 2021 20:00:58

**US3182114**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:31:05



**US3182114**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:05

**US3182114**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:05

**US3182114**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'OLD29'	System	17 Mar 2021 18:31:05

US3182114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53

US3182114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '13:36'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '23 Feb 2021 13:36'	System	17 Mar 2021 18:31:53



**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '97.8' F	(b) (4) Cassie Uminski (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered empty.	(b) (4)	17 Mar 2021 18:31:53
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '91'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'bpm'	System	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '16'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53

US3182114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'breaths/min'	System	17 Mar 2021 18:31:53

US3182114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '147'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53



**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mmHg'	System	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '84'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mmHg'	System	17 Mar 2021 18:31:53

US3182114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '15:01'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '23 Feb 2021 15:01'	System	17 Mar 2021 18:31:53



**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '97.6' F	(b) (4)	
	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53
	(b) (4)	

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered empty.	(b) (4)	17 Mar 2021 18:31:53
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '83'	Cassie Uminski (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'bpm'	System	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '15'	(b) (4) Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:31:53

US3182114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'breaths/min'	System	17 Mar 2021 18:31:53

US3182114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '131'	(b) (4) Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:31:53



**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mmHg'	System	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '79'	(b) (4) Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mmHg'	System	17 Mar 2021 18:31:53

**US3182114**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Mar 2021 18:32:10

**US3182114**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	17 Mar 2021 18:32:10

US3182114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:32:31

US3182114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered empty.	(b) (4)	17 Mar 2021 18:32:31
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered empty.	Cassie Uminski (b) (4)	17 Mar 2021 18:32:31



US3182114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mRNA-1273'	System	17 Mar 2021 18:32:31
DataPoint set to visible.	System	10 Feb 2021 20:00:58

US3182114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:32:31

US3182114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '14:31'	Cassie Uminski (b) (4)	17 Mar 2021 18:32:31

**US3182114**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:31:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '23 Feb 2021 14:31'	System	17 Mar 2021 18:32:31

US3182114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Left Arm (LEFT ARM)'	Cassie Uminski (b) (4)	17 Mar 2021 18:32:31

US3182114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'ONCE'	System	17 Mar 2021 18:32:31

US3182114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'INTRAMUSCULAR'	System	17 Mar 2021 18:32:31

**US3182114**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Mar 2021 18:32:17



**US3182114**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'I'	System	17 Mar 2021 18:32:17

**US3182114**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Mar 2021 18:34:40

**US3182114**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered '02 Mar 2021'	Cassie Uminski (b) (4)	17 Mar 2021 18:34:40

**US3182114**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	17 Mar 2021 18:34:40

**US3182114**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:31:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered empty.	Cassie Uminski (b) (4)	17 Mar 2021 18:34:40

**US3182114**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:34:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	17 Mar 2021 18:34:48

**US3182114**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:31:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'I'	System	17 Mar 2021 18:34:48

**US3182114**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Mar 2021 04:11:52



**US3182114**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '22 Mar 2021'	Cassie Uminski (b) (4)	28 Mar 2021 04:11:52

**US3182114**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	28 Mar 2021 04:11:52

**US3182114**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:31:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'OLD57'	System	28 Mar 2021 04:11:52

US3182114

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Mar 2021 04:12:09

US3182114

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '22 Mar 2021'	Cassie Uminski (b) (4)	28 Mar 2021 04:12:09

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '13:47'	Cassie Uminski (b) (4)	28 Mar 2021 04:12:09

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '22 Mar 2021 13:47'	System	28 Mar 2021 04:12:09

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '97.6' F	Cassie Uminski (b) (4)	28 Mar 2021 04:12:09



**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	28 Mar 2021 04:12:09

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered empty.	Cassie Uminski (b) (4)	28 Mar 2021 04:12:09

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '86'	Cassie Uminski (b) (4)	28 Mar 2021 04:12:09

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'bpm'	System	28 Mar 2021 04:12:09

US3182114

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '16'	Cassie Uminski (b) (4)	28 Mar 2021 04:12:09

US3182114

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'breaths/min'	System	28 Mar 2021 04:12:09

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '120'	Cassie Uminski (b) (4)	28 Mar 2021 04:12:09

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mmHg'	System	28 Mar 2021 04:12:09



**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '84'	Cassie Uminski (b) (4)	28 Mar 2021 04:12:09

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered 'mmHg'	System	28 Mar 2021 04:12:09

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05

**US3182114**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:31:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05

**US3182114**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Mar 2021 04:12:36

**US3182114**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:31:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered '22 Mar 2021'	Cassie Uminski (b) (4)	28 Mar 2021 04:12:36

**US3182114**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	28 Mar 2021 04:13:06

US3182114

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per Preclarus report, Sample recorded under OL-D57 is dated 22MAR2021 is in EDC, however the same is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).		19 Apr 2021 09:43:21
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per Preclarus report, Sample recorded under OL-D57 is dated 22MAR2021 is in EDC, however the same is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' answered with 'Confirmed sent ' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 18:37:07
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per Preclarus report, Sample recorded under OL-D57 is dated 22MAR2021 is in EDC, however the same is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:43:15
User signature succeeded.	Mary Beth Manning (b) (4)	28 Mar 2021 21:42:07
User entered '22 Mar 2021'	Cassie Uminski (b) (4) (b) (4)	28 Mar 2021 04:13:06



US3182114

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User signature succeeded.	Mary Beth Manning	09 Apr 2021 15:31:18
Signature has been broken.	(b) (4)	08 Apr 2021 18:36:55
	Cassie Uminski (b) (4)	08 Apr 2021 18:36:55
User entered '14:06' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 18:36:55
User signature succeeded.	Mary Beth Manning	28 Mar 2021 21:42:07
	(b) (4)	
User entered '13:55'	Cassie Uminski (b) (4)	28 Mar 2021 04:13:06
	(b) (4)	

**US3182114**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:31:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:59:05
User entered '22 Mar 2021 14:06'	System	08 Apr 2021 18:36:55
User entered '22 Mar 2021 13:55'	System	28 Mar 2021 04:13:06

US3182114

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:31:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:25
User closed query 'Per DM CLR: Per Day 236 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).		12 Apr 2021 14:40:27
Query 'Per DM CLR: Per Day 236 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'AE's updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 18:41:27
User opened query 'Per DM CLR: Per Day 236 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:19:04
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 15:25:34
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	09 Mar 2021 13:43:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	09 Mar 2021 13:43:40
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:18:48
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Feb 2021 17:00:27

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26

US3182114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 13:45:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 13:45:57
Data point term sent to Coder	System	09 Mar 2021 13:45:22
User entered 'Headache'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

US3182114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Mar 2021 13:48:16
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01



US3182114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '16 Nov 2020'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User entered empty.	System	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '24 Nov 2020'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

US3182114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User entered empty.	System	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01



US3182114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

US3182114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

US3182114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'None (NONE)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'I'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User entered '0'	System	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26
User entered '0'	System	09 Mar 2021 13:45:01

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:26

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of SEASONAL ALLERGIES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).		30 Mar 2021 08:11:55
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of SEASONAL ALLERGIES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'Data is correct as is' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	28 Mar 2021 03:56:22
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of SEASONAL ALLERGIES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 07:18:32
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 15:25:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:46:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:46:56
Data point term sent to Coder	System	09 Mar 2021 13:46:23
User entered 'Sinus congestion'	Cassie Uminski (b) (4) (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '16 Nov 2020'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User entered empty.	System	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '26 Nov 2020'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User entered empty.	System	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

US3182114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'None (NONE)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'I'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:45:56



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User entered '0'	System	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38
User entered '0'	System	09 Mar 2021 13:45:56

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:38:38

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 15:38:20
User entered		
'USA-US075-2021-mRNA-1273-P301000013'	System	09 Apr 2021 15:37:33
User entered 'New'	(b) (4), (b) (6)	09 Apr 2021 15:37:33

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:56:42
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).		23 Apr 2021 19:56:42
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'Pending Medical Records ' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 19:26:30
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 18:52:06
User signature succeeded.	Mary Beth Manning (b) (4)	09 Apr 2021 12:47:32
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 18:35:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 18:35:49
Data point term sent to Coder	System	08 Apr 2021 18:34:19
User entered 'Abdominal Pain'	Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 18:33:51

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	



US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '05 Apr 2021'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:33:51

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	15 Apr 2021 18:50:07
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 18:33:51

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:33:51

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	



US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 10:49:51
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject has not been discharged at this time' (Site from System).	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	Cassie Uminski (b) (4)	08 Apr 2021 18:35:11
User entered '1'	(b) (4)	
	System	08 Apr 2021 18:33:51
	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '06 Apr 2021'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 18:49:51
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 18:33:51

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	



US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'I'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Outcome](#)

Audit	User	Time (GMT)
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)	15 Apr 2021 18:51:37
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
User entered 'Unknown (UNKNOWN)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Apr 2021 18:33:51

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:10

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 18:51:17
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		15 Apr 2021 18:50:52
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		15 Apr 2021 18:49:26
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
User entered 'Clinical site staff called subject after we received an alert that subject reported in his day 236 diary form that he had contact with his healthcare provider. Subject confirmed that he is currently admitted to hospital. Subject states he actually presented to ER on 05-Apr-2021 with complaints of fever and chills. subject was admitted on 06-Apr-2021. Subject reports symptoms of abdominal pain, fever, fatigue. information will be updated when records are received after discharge.'	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 18:33:51
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 18:33:51

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:33:51

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 18:33:51

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle injury, LLT: Muscle injury - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 03:07:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 03:07:29
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 03:04:28
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 03:04:28
	(b) (4)	
Data point term sent to Coder	System	08 Apr 2021 18:37:27
User entered 'Calf tear'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '16 Mar 2021'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:36:37

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:36:37

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	



US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'None (NONE)'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'I'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

US3182114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:31:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	08 Apr 2021 18:36:37
	(b) (4)	

**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 18:36:37



**US3182114**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 18:36:37

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:31:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:41:14

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 15:43:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 15:43:01
Data point term sent to Coder	System	05 Aug 2020 15:42:28
User entered 'Alprazolam'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:41:49

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Anxiety'	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '5'	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:30:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 15:41:49
User entered 'un UNK 2015'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:41:49

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	



US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:41:49
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 15:41:49

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 15:41:49

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 15:41:49

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 15:45:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 15:45:59
Data point term sent to Coder	System	05 Aug 2020 15:44:29
User entered 'Lisinopril'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:43:44

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'hypertension'	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '20'	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	



US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:21:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 15:43:44
User entered 'un UNK 2019'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:43:44

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:43:44
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 15:43:44

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 15:43:44

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 15:43:44

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 15:45:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 15:45:59
Data point term sent to Coder	System	05 Aug 2020 15:45:30
User entered 'Pravastatin'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:44:51

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'High Cholesterol'	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '40'	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	



US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:21:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 15:44:51
User entered 'un UNK 2015'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:44:51

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:44:51
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 15:44:51

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 15:44:51

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 15:44:51



US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: TEMAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 17:44:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:44:07
Data point term sent to Coder	System	05 Aug 2020 15:45:30
User entered 'Temazepam'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:45:21

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Depression'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '30'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:31:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:31:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:21:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 15:45:21
User entered 'un UNK 2015'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:45:21

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:21
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 15:45:21



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 15:45:21

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 15:45:21

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE, PRODUCTSYNONYM: TRUVADA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 15:47:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 15:47:03
Data point term sent to Coder	System	05 Aug 2020 15:46:30
User entered 'Truvada'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:45:50

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	05 Aug 2020 15:46:00
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'HIV PREP'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '300'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:31:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	



US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:31:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:21:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 15:45:50
User entered 'un UNK 2018'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:45:50

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:31:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	



US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:45:50
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 15:45:50

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 15:45:50

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 15:45:50

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VILAZODONE HYDROCHLORIDE, PRODUCTSYNONYM: VIIBRYD - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 15:48:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 15:48:03
Data point term sent to Coder	System	05 Aug 2020 15:47:30
User entered 'Viibryd'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:46:36

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Depression'	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '20'	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	



US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

US3182114

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 15:21:31
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 15:46:36
User entered 'un UNK 2019'	Cassie Uminski (b) (4) (b) (4)	05 Aug 2020 15:46:36

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	05 Aug 2020 15:46:36
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 15:46:36

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 15:46:36

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 15:46:36

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 20:07:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:07:26
Data point term sent to Coder	System	06 Nov 2020 20:06:14
User entered 'Influenza Vaccine'	Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 20:06:07

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Yes (Y)'	(b) (4)	06 Nov 2020 20:06:07
	Cassie Uminski (b) (4)	
	(b) (4)	



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	06 Nov 2020 20:06:07

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'I'	Cassie Uminski (b) (4)	06 Nov 2020 20:06:07

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	06 Nov 2020 20:06:07

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'injection'	Cassie Uminski (b) (4)	06 Nov 2020 20:06:07

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 20:06:07

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	06 Nov 2020 20:06:07
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 20:06:07

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	06 Nov 2020 20:06:07
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '15 Oct 2020'	Cassie Uminski (b) (4)	06 Nov 2020 20:06:07

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Cassie Uminski (b) (4)	06 Nov 2020 20:06:07

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'No (N)'	(b) (4)	06 Nov 2020 20:06:07
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '15 Oct 2020'	Cassie Uminski (b) (4)	06 Nov 2020 20:06:07

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'No (N)'	(b) (4)	06 Nov 2020 20:06:07
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User entered empty.	System	06 Nov 2020 20:06:07

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User entered empty.	System	06 Nov 2020 20:06:07

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:14
User entered empty.	System	06 Nov 2020 20:06:07



US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 20:11:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:11:20
Data point term sent to Coder	System	06 Nov 2020 20:10:21
User entered 'Ibuprofen'	Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 20:10:16

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'No (N)'	(b) (4)	06 Nov 2020 20:10:16
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:37:33
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'Does not meet AE reporting criteria' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:17:19



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '400'	Cassie Uminski (b) (4)	06 Nov 2020 20:10:16

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 20:10:16

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	06 Nov 2020 20:10:16
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	06 Nov 2020 20:10:16



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:31:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4)	06 Nov 2020 20:10:16
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	06 Nov 2020 20:10:16

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 20:10:16

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '02 Aug 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 20:10:16

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '0'	Cassie Uminski (b) (4)	06 Nov 2020 20:10:16

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered 'No (N)'	(b) (4)	06 Nov 2020 20:10:16
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User entered '03 Aug 2020'	Cassie Uminski (b) (4)	06 Nov 2020 20:10:16

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe. Please review if the response in this field should be updated to YES. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 14:37:28
Query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe. Please review if the response in this field should be updated to YES. Update as appropriate. Otherwise, provide clarification.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:17:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	01 Feb 2021 16:17:06
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe. Please review if the response in this field should be updated to YES. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:26:02
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	06 Nov 2020 20:10:16



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User entered '1'	System	06 Nov 2020 20:10:16

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User entered '1'	System	06 Nov 2020 20:10:16

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:15
User entered '804 (804)'	System	06 Nov 2020 20:10:16

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Apr 2021 12:47:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 18:46:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 18:46:45
Data point term sent to Coder	System	08 Apr 2021 18:45:49
User closed query 'CDM-Coding: Please enter the active ingredient(s) of drug name SUDAFED in drug name field and please make your changes to the reported term. Thank you.	System	08 Apr 2021 18:44:58
' (Site from System).		
Query 'CDM-Coding: Please enter the active ingredient(s) of drug name SUDAFED in drug name field and please make your changes to the reported term. Thank you.	Cassie Uminski (b) (4)	08 Apr 2021 18:44:58
' answered with 'Updated' (Site from System).	(b) (4)	
Coding entries removed.	Cassie Uminski (b) (4)	08 Apr 2021 18:44:52
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 18:44:52
User entered 'SUDAFED (Pseudoephedrine)' reason for change: Data Entry Error	(b) (4)	
	Cassie Uminski (b) (4)	08 Apr 2021 18:44:52
User opened query 'CDM-Coding: Please enter the active ingredient(s) of drug name SUDAFED in drug name field and please make your changes to the reported term. Thank you.	Coder Import (b) (4)	06 Apr 2021 12:15:09
' (Site from System).	(b) (4)	
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 13:47:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 13:47:56
Data point term sent to Coder	System	09 Mar 2021 13:47:23
User entered 'Sudafed'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Sinus congestion'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '220'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22



US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'mg (mg)'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	(b) (4)	09 Mar 2021 13:47:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	(b) (4)	09 Mar 2021 13:47:22
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '16 Nov 2020'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22



US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:31:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '26 Nov 2020'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:22

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	(b) (4)	09 Mar 2021 13:47:22
	Cassie Uminski (b) (4)	
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User entered '1'	System	09 Mar 2021 13:47:22

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User entered '1'	System	09 Mar 2021 13:47:22

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:05:14
User entered '804 (804)'	System	09 Mar 2021 13:47:22

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 13:48:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Mar 2021 13:48:56
Data point term sent to Coder	System	09 Mar 2021 13:48:24
User entered 'Advil'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:48
	(b) (4)	

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:31:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	(b) (4)	
	Cassie Uminski (b) (4)	09 Mar 2021 13:47:48
	(b) (4)	



**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:31:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Headache'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Mar 2021 13:47:48

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:31:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '500'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:48

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Mar 2021 13:47:48

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	(b) (4)	09 Mar 2021 13:47:48
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:48

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	(b) (4)	09 Mar 2021 13:47:48
	Cassie Uminski (b) (4)	
	(b) (4)	

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:48

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered empty.	(b) (4)	09 Mar 2021 13:47:48
	Cassie Uminski (b) (4)	
	(b) (4)	



US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '16 Nov 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Mar 2021 13:47:48

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Mar 2021 13:47:48

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Mar 2021 13:47:48

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered '24 Nov 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	09 Mar 2021 13:47:48

US3182114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 15:25:34
User entered 'No (N)'	Cassie Uminski (b) (4)	09 Mar 2021 13:47:48

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:31:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User entered '1'	System	09 Mar 2021 13:47:48

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User entered '1'	System	09 Mar 2021 13:47:48

**US3182114**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:31:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:19:21
User entered '804 (804)'	System	09 Mar 2021 13:47:48



US3182114

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 15:31:10**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:18:48
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	04 Feb 2021 17:00:39
	(b) (4)	

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered	System	09 Apr 2021 15:37:33
'USA-US075-2021-MRNA-1273-P301000013'		

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'Yes (Y)'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'No (N)'	System	09 Apr 2021 15:37:33

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'No (N)'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'Yes (Y)'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'No (N)'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'No (N)'	System	09 Apr 2021 15:37:33



US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'No (N)'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'Toby'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'Briskin'	System	09 Apr 2021 15:37:33

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered '3619 Park East Drive, Suite 300'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'Beachwood'	System	09 Apr 2021 15:37:33

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'OH'	System	09 Apr 2021 15:37:33

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered '44122'	System	09 Apr 2021 15:37:33

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
User entered 'US'	System	09 Apr 2021 16:00:12



**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 16:00:12

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered	System	09 Apr 2021 15:37:33
'USA-US075-2021-MRNA-1273-P301000013'		

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'Yes (Y)'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'No (N)'	System	09 Apr 2021 15:37:33

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'No (N)'	System	09 Apr 2021 15:37:33

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'Yes (Y)'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'No (N)'	System	09 Apr 2021 15:37:33

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'No (N)'	System	09 Apr 2021 15:37:33



**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'No (N)'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'Toby'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'Briskin'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered '3619 Park East Drive, Suite 300'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'Beachwood'	System	09 Apr 2021 15:37:33

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:10

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered 'OH'	System	09 Apr 2021 15:37:33

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 16:00:04
User entered '44122'	System	09 Apr 2021 15:37:33

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
User entered 'US'	System	09 Apr 2021 16:00:12



**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:31:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 16:00:12

**US3182114**

**Folder: SAE USA-US075-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:31:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
User entered '09/Apr/2021 12:00'	System	09 Apr 2021 16:00:12

US3182114

Folder: SAE USA-US075-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:31:10

**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)	13 Apr 2021 13:49:58
User signature succeeded.	Toby Briskin (b) (4)	09 Apr 2021 17:43:52
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 16:00:12