

US3412300 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:37:03

All time stamps listed in this document are displayed in GMT

**US3412300**

**Form: Participant Creation**

**Data signed:** (b) (4) 16 Apr 2021 18:18:16

**Generated On: 11 Aug 2021 22:37:03**

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[Participant ID](#)

US3412300

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

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US3412300

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:21:35

Generated On: 11 Aug 2021 22:37:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3412300

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 12:21:24

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" 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) 13 Feb 2021 12:21:24

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 12:21:24

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 12:21:24

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Condition	ALLERGIC - MEDICATIONS - TETRACYCLINE AND DOXYCYCLINE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 12:21:24

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Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 12:21:35

Generated On: 11 Aug 2021 22:37:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	7:55 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 7:55
Height (xxx.x)	168.8 cm
Weight (xxx.x)	119.3 kg
BMI (xxx.x)	41.86929 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 12:21:24

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Date of assessment (dd MMM yyyy) 24 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☒  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 12:21:24

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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**

(b) (6) OPERATIONS SUPPORT  
STAFF SEES NUMEROUS  
PEOPLE (20 OR MORE A DAY.

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

**No Risk Identified** False

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

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PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 12:21:24

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

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

Visit date (dd MMM yyyy)	24 AUG 2020
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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	VISIT1
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US3412300

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 144385

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

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)	24 AUG 2020
Time of assessment (00:00-23:59)	7:55 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 7:55
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

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)	24 AUG 2020
Time of assessment (00:00-23:59)	8:55 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 8:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

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) 13 Feb 2021 12:21:35

Generated On: 11 Aug 2021 22:37:03

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 08:20 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 08:20

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:21:35

Generated On: 11 Aug 2021 22:37:03

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

Collection date (dd MMM yyyy)	24 AUG 2020
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Collection time (00:00-23:59)	08:04 (24 HR)
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Collection date and time (derived)	24 AUG 2020 08:04
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US3412300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 12:21:35

Generated On: 11 Aug 2021 22:37:03

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:09	24 AUG 2020 08:09
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:21:35

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**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

97.7 °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

24 AUG 2020 08:53

PC Open Date & Time

24 AUG 2020 08:40

PC Close Date & Time

24 AUG 2020 11:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**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	24 AUG 2020 18:07
PC Open Date & Time	24 AUG 2020 12:05
PC Close Date & Time	25 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 13:29

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

26 AUG 2020 14:08

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 16:41

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:03

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 12:02

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**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

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

29 AUG 2020 18:34

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

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

30 AUG 2020 21:58

---

PC Open Date & Time

30 AUG 2020 12:00

---

PC Close Date & Time

31 AUG 2020 11:59

---



US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 08:54

PC Open Date & Time

24 AUG 2020 08:40

PC Close Date & Time

24 AUG 2020 11:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**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

24 AUG 2020 18:07

PC Open Date & Time

24 AUG 2020 12:05

PC Close Date & Time

25 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**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

25 AUG 2020 13:29

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

**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

26 AUG 2020 14:08

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**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

27 AUG 2020 16:42

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:03

**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

28 AUG 2020 12:02

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**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

29 AUG 2020 18:34

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT	DAY 7
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	30 AUG 2020 21:58
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59



US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**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 ☐

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 08:55
PC Open Date & Time	24 AUG 2020 08:40
PC Close Date & Time	24 AUG 2020 11:10

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**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 ☐

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 18:08
PC Open Date & Time	24 AUG 2020 12:05
PC Close Date & Time	25 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 13:30
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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  
EAB) (1725)

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US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:03

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 14:09
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59



US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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 ☒

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

		Yes <input type="checkbox"/>
PC Time stamp	27 AUG 2020 16:43	
PC Open Date & Time	27 AUG 2020 12:00	
PC Close Date & Time	28 AUG 2020 11:59	

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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)

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 18:34
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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

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EAB) (1725)

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 21:59
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59



US3412300

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412300

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

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*

US3412300

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412300

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

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

US3412300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

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)	21 SEP 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 08:15
Temperature (xxx.x)	36.4 C
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)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG



US3412300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:50
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412300

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3412300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 09:15 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 09:15

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

US3412300

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

08:38 (24 HR)

Collection date and time (derived)

21 SEP 2020 08:38

US3412300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:33	21 SEP 2020 08:33
Nasopharyngeal Swab 2	No		

US3412300

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 09:50

PC Open Date & Time

21 SEP 2020 09:35

PC Close Date & Time

21 SEP 2020 12:05

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**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	21 SEP 2020 18:21
PC Open Date & Time	21 SEP 2020 13:00
PC Close Date & Time	22 SEP 2020 11:59



US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 17:05

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

23 SEP 2020 16:14

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PC Open Date & Time

23 SEP 2020 12:00

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PC Close Date & Time

24 SEP 2020 11:59

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US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 19:13

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 18:56

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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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 ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 19:46

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

27 SEP 2020 21:08

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**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

21 SEP 2020 09:51

PC Open Date & Time

21 SEP 2020 09:35

PC Close Date & Time

21 SEP 2020 12:05

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**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

21 SEP 2020 18:22

PC Open Date & Time

21 SEP 2020 13:00

PC Close Date & Time

22 SEP 2020 11:59



US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**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

22 SEP 2020 17:05

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

**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

23 SEP 2020 16:14

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**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

24 SEP 2020 14:07

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:03

**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

25 SEP 2020 18:57

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**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

26 SEP 2020 19:46

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**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

27 SEP 2020 21:08

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**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 ☐

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 09:51
PC Open Date & Time	21 SEP 2020 09:35
PC Close Date & Time	21 SEP 2020 12:05



US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**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 ☐

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 18:22
PC Open Date & Time	21 SEP 2020 13:00
PC Close Date & Time	22 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 17:05
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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  
EAB) (1725)

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**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 16:14
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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 ☒

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EAB) (1725)

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 14:07
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59



US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:57
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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)

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 19:47
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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 ☒

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 21:08
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3412300

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412300

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3412300

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412300

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412300

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:21:24

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

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

US3412300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

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

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

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

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

US3412300

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

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.*

US3412300

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

07:20 (24 HR)

Collection date and time (derived)

19 OCT 2020 07:20



US3412300

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:21:36

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 04:55:29

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3412300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

31 OCT 2020 07:40:25

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3412300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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	07 NOV 2020 14:48:08
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59



US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2020 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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 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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2020 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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20 DEC 2020 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 DEC 2020 13:15:19
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

30 DEC 2020 02:37:56

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59



US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 JAN 2021 05:36:42
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 06:12:57

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

20 JAN 2021 13:20:07

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

27 JAN 2021 12:52:56

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 05:19:29

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

10 FEB 2021 05:21:35

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

17 FEB 2021 06:02:04

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

24 FEB 2021 11:08:52

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59



US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 MAR 2021 08:08:42

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

<b>TIMEPOINT</b>	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 04:25:43
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

17 MAR 2021 09:24:28

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

24 MAR 2021 06:08:13

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

31 MAR 2021 04:38:03

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

07 APR 2021 07:50:26

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 06:11:05

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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

21 APR 2021 10:25:33

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59



US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 08:43:56

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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="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"/>



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

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27 JUN 2021 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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="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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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 <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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

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25 JUL 2021 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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="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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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="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"/>



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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 <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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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"/>



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 460

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

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

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

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

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

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30 JAN 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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06 FEB 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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 <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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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20 FEB 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

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27 FEB 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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06 MAR 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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09 MAR 2022 00:01

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13 MAR 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

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**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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06 APR 2022 00:01

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10 APR 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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="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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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"/>



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

DAY 684

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

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

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

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

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

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

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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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06 JUL 2022 00:01

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10 JUL 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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20 JUL 2022 00:01

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24 JUL 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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31 JUL 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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 <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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

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07 AUG 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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14 AUG 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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28 AUG 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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04 SEP 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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11 SEP 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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="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"/>



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

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18 SEP 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

**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 ☐



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

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US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

US3412300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:03

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"/>

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

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

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[Patient Cloud Open Date & Time](#)

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26 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 OCT 2022 23:59

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**US3412300**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 22:37:03**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 22:05:35

US3412300

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:41:08

Generated On: 11 Aug 2021 22:37:03

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*

SUBJECT WAS IN  
CONVALESCENT PERIOD  
DURING THIS SAFETY CALL  
AND THEREFOR SITE WAS  
CONDUCTING DAILY SAFETY  
CALLS WHICH REPLACED ANY  
MONTHLY PHONE CALLS.

US3412300

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:41:08

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3412300

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412300

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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*

PATIENT WAS IN OL PHASE  
AND NOT CALLED DUE TO SITE  
ERROR. SITE STAFF  
INSTRUCTED TO COMPLETE  
REGULAR SAFETY CALLS  
ALONGSIDE OPEN LABEL  
CALLS

US3412300

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412300

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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

Visit date (dd MMM yyyy)	22 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3412300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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)	08:11 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 08:11
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3412300

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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.*

US3412300

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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

Collection date (dd MMM yyyy)	22 MAR 2021
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Collection time (00:00-23:59)	08:18 (24 HR)
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Collection date and time (derived)	22 MAR 2021 08:18
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US3412300

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3412300**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

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*

**US3412300**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 18:18:16

Generated On: 11 Aug 2021 22:37:03

Date of Contact	04 NOV 2020
Time of Contact	15:30
Date and Time of Contact (derived)	04 NOV 2020 15:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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"/>

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	37.7 C	
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 04 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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"/>

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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"/>

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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"/>

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.8 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 04 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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 (2)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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 (3)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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 (3)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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 (4)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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 (4)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.9 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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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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 (5)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.1 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 (6)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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 04 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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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Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	85 %	
O2 Saturation Units	%	
Temperature	99.1 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 (7)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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 04 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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 04 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.1 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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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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

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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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 04 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.1 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 (9)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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 04 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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 (10)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 (10)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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 (10)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 04 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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 (11)

Data signed: (b) (4) 16 Apr 2021 18:18:17

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Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 (12)

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Generated On: 11 Aug 2021 22:37:03

	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) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<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 (13)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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	95 %
---------------	------

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

Temperature	98.7 F
-------------	--------

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

Cough	None <input 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 (15)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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 (15)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

Symptom Day

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

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Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

	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"/>

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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 ☐

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 18:18:16

Generated On: 11 Aug 2021 22:37:03

Date of Visit	04 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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	04 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)	1

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:16

Generated On: 11 Aug 2021 22:37:03

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

If Yes, provide:

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

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

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

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

If Yes, provide:

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

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

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

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

If Yes, provide:

Start Date 10 NOV 2020

End Date 10 NOV 2020

Oxygen Saturation 85 %

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

If Yes, provide:

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

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

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

Did the subject have Respiratory failure? Yes ☐ No ☒

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

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

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

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:16

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

**Ventilator Support:**

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:16

Generated On: 11 Aug 2021 22:37:03

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

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

Start Date

End Date

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:17

Generated On: 11 Aug 2021 22:37:03

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 16 Apr 2021 18:18:17

**Generated On: 11 Aug 2021 22:37:03**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	6 NOV 2020
Day 5	Yes	08 NOV 2020
Day 7	Yes	10 NOV 2020
Day 9	Yes	12 NOV 2020
Day 14	Yes	17 NOV 2020
Day 21	Yes	24 NOV 2020
Day 28	Yes	02 DEC 2020

US3412300

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3412300

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 NOV 2020
Time of assessment (00:00-23:59)	15:44 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 15:44
Height (xxx.x)	168.5 cm
Weight (xxx.x)	120.2 kg
Temperature (xxx.x)	37.7 C
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)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412300

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 NOV 2020

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

US3412300

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

04 NOV 2020



US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:16

Generated On: 11 Aug 2021 22:37:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:18:16

Generated On: 11 Aug 2021 22:37:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 DEC 2020
Time of assessment (00:00-23:59)	08:25 (24 HR)
Vital Signs Date and Time (derived)	2 DEC 2020 08:25
Height (xxx.x)	172 cm
Weight (xxx.x)	122.7 kg
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:16

Generated On: 11 Aug 2021 22:37:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 DEC 2020

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

US3412300

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 16 Apr 2021 18:18:16

Generated On: 11 Aug 2021 22:37:03

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 DEC 2020

US3412300

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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

Visit date (dd MMM yyyy)	14 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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US3412300

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Date of updated informed consent ( <i>dd MMM yyyy</i> )	14 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> )	14 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

**US3412300**

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

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 16 Apr 2021 18:18:18

**Generated On: 11 Aug 2021 22:37:03**

Height	170.2 cm
Weight	120.9 kg
BMI (xxx.x)	41.73565

US3412300

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Height	170.2 cm
Weight	120.9 kg
BMI (xxx.x)	41.73565
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)	14 JAN 2021
Time of assessment (00:00-23:59)	08:03 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 08:03
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG



US3412300

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Height	170.2 cm
Weight	120.9 kg
BMI (xxx.x)	41.73565
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)	14 JAN 2021
Time of assessment (00:00-23:59)	08:58 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 08:58
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3412300

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3412300

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 08:22 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 08:22

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

US3412300

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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

Collection date (dd MMM yyyy)	14 JAN 2021
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Collection time (00:00-23:59)	08:15 (24 HR)
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Collection date and time (derived)	14 JAN 2021 08:15
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US3412300

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	08:10
Collection Date and Time (derived)	14 JAN 2021 08:10

US3412300

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:41:08

Generated On: 11 Aug 2021 22:37:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412300

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:41:08

Generated On: 11 Aug 2021 22:37:03

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



US3412300

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3412300

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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)	11 FEB 2021
Time of assessment (00:00-23:59)	07:25 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 07:25
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412300

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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)	11 FEB 2021
Time of assessment (00:00-23:59)	08:36 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 08:36
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412300

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3412300

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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) 11 FEB 2021

What was the treatment time? (00:00-23:59) 08:03 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 08:03

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

What was the frequency of the study treatment dosing? ONCE

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

US3412300

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412300

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:41:08

Generated On: 11 Aug 2021 22:37:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412300

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:41:08

Generated On: 11 Aug 2021 22:37:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3412300

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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

US3412300

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	08:11 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 08:11
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412300

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

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.*

US3412300

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 MAR 2021

Collection time (00:00-23:59)

08:18 (24 HR)

Collection date and time (derived)

22 MAR 2021 08:18

US3412300

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:40:45

Generated On: 11 Aug 2021 22:37:03

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3412300

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:40:45

Generated On: 11 Aug 2021 22:37:03

AEID	USA-US061-2020-MRNA-1273-P30 1000008
Adverse event	SYMPTOMATIC COVID -19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	2 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3412300

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:40:45

Generated On: 11 Aug 2021 22:37:03

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 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	

US3412300

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:40:45

Generated On: 11 Aug 2021 22:37:03

---

SUBJECT WAS EXPOSED TO  
COWORKERS WHO TESTED  
POSITIVE FOR COVID  
26OCT2020. SUBJECT  
REPORTED MILD DRY COUGH,  
HEADACHES, CONGESTION,  
FEVER (100.1 F) AND SNIFFLES  
ON 02 NOV2020. EVERY  
SYMPTOM RESOLVED BY  
03-NOV-2020 EXCEPT A FEVER .  
ON 04-NOV-2020 THE FEVER  
HAD BROKE AND WAS <38.0  
DEGREES CELSIUS. THERE WAS  
NO TREATMENT  
ADMINISTERED BY THE  
SUBJECT. REPORTED ON VISIT  
NOTES THAT SUBJECT DOIN  
WELL WITGH NO REPORTS OF  
ANY SYMPTOMS ON  
05-06-07-08-NOV-2020.  
09-NOV-2020 SUBJECT  
INFORMED OF TEST RESULTS  
AND DAY 28 VISIT SCHEDULED  
FOR 02-DEC-2020 AT 0700.  
SUBJECT REPORTS FEELING  
WELL WITH NO C/O  
SYMPTOMS. 10-NOV-2020  
SUBJECT REPORTS FEELING  
WELL WITH NO NEW  
SYMPTOMS BUT STATED  
OXYGEN SATURATION WAS  
85% WAS ONLY FOR A FEW  
MOMENTS. SUBJECT OXYGEN  
SATURATION DURING PHONE  
CALL WAS 96%. FROM  
11-NOV-2020 TO 17-NOV-2020  
SUBJECT FEELING WELL WITH  
NO SYMPTOMS TO REPORT.  
STOPPED TELEMEDICINE VISIT  
CALLS. SUBJECT REPORTED  
FOR DAY 28 VISIT ON  
02-DEC-2020 AND TOLERATED  
ALL PROCEDURES. AE CLOSED

---



**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed:** (b) (4) 15 Mar 2021 15:40:45

**Generated On: 11 Aug 2021 22:37:03**

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3412300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:44:14

Generated On: 11 Aug 2021 22:37:03

---

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

Yes ☒

No ☐

---

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

---

US3412300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:26:02

Generated On: 11 Aug 2021 22:37:03

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 0.5

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

US3412300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:26:02

Generated On: 11 Aug 2021 22:37:03

	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)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		7 DEC 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"/>

US3412300

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:44:15

Generated On: 11 Aug 2021 22:37:03

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3412300

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:37:03

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3412300

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:37:03

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 ☐

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

SAEID	USA-US061-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6



US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

SAEID	USA-US061-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/NOV/2020 19:07
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

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

SAEID	USA-US061-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	20/NOV/2020 19:12
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

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

SAEID	USA-US061-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/DEC/2020 08:57
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

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

SAEID	USA-US061-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/DEC/2020 20:30
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

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

SAEID	USA-US061-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/DEC/2020 12:55
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

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 18:18:18

Generated On: 11 Aug 2021 22:37:03

SAEID	USA-US061-2020-MRNA-1273-P301000008
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/MAR/2021 20:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412300 (Prod: New Horizons Clinical Research)

**US3412300**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:37:03**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:31:32
User entered 'US3412300'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 11:24:42



**US3412300**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:31:42
User entered 'Yes (Y)'		24 Aug 2020 12:13:21

**US3412300**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:31:42
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 11:24:43

**US3412300**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:31:42
User entered 'Clinic (Clinic)'		24 Aug 2020 12:13:21

**US3412300**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'SCRN'	System	24 Aug 2020 12:13:21

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 11:24:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4)	08 Oct 2020 15:34:09
User entered '59'	(b) (4), (b) (6)	24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'YEARS'	System	24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered '59'	System	24 Aug 2020 12:14:09



US3412300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:37:03

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:34:09
User closed query 'Per CDM, The sex is 'Female'. However Childbearing potential page has not filled. Please complete the page' (Site from DM).	(b) (4)	29 Sep 2020 19:26:51
Query 'Per CDM, The sex is 'Female'. However Childbearing potential page has not filled. Please complete the page' answered with 'UPDATED' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:47:38
User opened query 'Per CDM, The sex is 'Female'. However Childbearing potential page has not filled. Please complete the page' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 04:04:34
User entered 'Female (F)'		24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'		24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered 'l'		24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered '0'		24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered '0'		24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered '0'		24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered '0'		24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered '0'		24 Aug 2020 12:13:44



**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered empty.		24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered '0'		24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:03**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:34:09
User entered '0'		24 Aug 2020 12:13:44

**US3412300**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:32:04
User entered '24 Aug 2020'		24 Aug 2020 12:14:09

**US3412300**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:03**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'Aug 2020'	System	24 Aug 2020 12:14:09

**US3412300**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:03**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered '2020'	System	24 Aug 2020 12:14:09

**US3412300**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:03**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:32:04
User entered 'Amendment 2 (2)'		24 Aug 2020 12:14:09

**US3412300**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:03**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:32:04
User entered 'Yes (Y)'		24 Aug 2020 12:14:09



**US3412300**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:03**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:32:04
User entered empty.		24 Aug 2020 12:14:09

**US3412300**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:03**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4)	08 Oct 2020 15:32:04
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:14:09

**US3412300**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:03**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:32:04
User entered 'No (N)'		24 Aug 2020 12:14:09

**US3412300**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:03**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:32:04
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 11:24:43

**US3412300**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:03**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'I'	System	24 Aug 2020 12:14:24

**US3412300**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 22:37:03**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:32:36
User entered 'Yes (Y)'		24 Aug 2020 12:14:24

**US3412300**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 22:37:03**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:32:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 20:40:03
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:42:26

US3412300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:37:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:33:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:45:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:45:20
Data point term sent to Coder	System	28 Sep 2020 20:42:01
User entered 'ALLERGIC - MEDICATIONS - TETRARYCLINE AND DOXYCYCLINE'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:41:21



US3412300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:37:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	25 Oct 2020 22:39:07
User closed query 'start date 2017 per source? Please confirm and update as appropriate' (Site from CRA).		25 Oct 2020 22:39:05
Query 'start date 2017 per source? Please confirm and update as appropriate' answered with 'UPDATED' (Site from CRA).	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:38:32
User entered 'UN UNK 2017' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:38:16
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 15:33:57
DataPoint Verified.		08 Oct 2020 15:33:55
User opened query 'start date 2017 per source? Please confirm and update as appropriate' (Site from CRA).		08 Oct 2020 15:33:48
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:41:21

US3412300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:37:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Oct 2020 22:39:08
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	09 Oct 2020 13:38:25
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:38:25
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:38:25
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	09 Oct 2020 13:38:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:33:55
User entered '1'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:41:21

**US3412300**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:33:55
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:41:21

**US3412300**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:33:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:41:21

**US3412300**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:33:55
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:41:21

**US3412300**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'Jan 2017'	System	09 Oct 2020 13:38:16
User entered empty.	System	28 Sep 2020 20:41:21

**US3412300**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered '2017'	System	09 Oct 2020 13:38:16
User entered empty.	System	28 Sep 2020 20:41:21

**US3412300**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered empty.	System	28 Sep 2020 20:41:21



**US3412300**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered empty.	System	28 Sep 2020 20:41:21

US3412300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:37:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:39
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:38:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:38:32
Data point term sent to Coder	System	09 Oct 2020 13:37:16
User entered 'POSTMENOPAUSAL'	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:37:10

**US3412300**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:39
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:37:10

**US3412300**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:39
User entered '0'	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:37:10

**US3412300**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:39
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:37:10

**US3412300**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:03**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:39
User entered empty.	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:37:10

**US3412300**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:06:39
User entered '0'	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:37:10

**US3412300**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'Jan 2010'	System	09 Oct 2020 13:37:10



**US3412300**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered '2010'	System	09 Oct 2020 13:37:10

**US3412300**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered empty.	System	09 Oct 2020 13:37:10

**US3412300**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered empty.	System	09 Oct 2020 13:37:10

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered '24 Aug 2020'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered '7:55'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered '24 Aug 2020 7:55'	System	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered '168.8' cm	Mylene Asmar-Rios	31 Aug 2020 17:43:52
DataPoint set to visible.	(b) (4) System	24 Aug 2020 12:14:24



**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered '119.3' kg	Mylene Asmar-Rios	31 Aug 2020 17:43:52
DataPoint set to visible.	(b) (4) System	24 Aug 2020 12:14:24

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered '41.86929'	System	31 Aug 2020 17:43:52
DataPoint set to visible.	System	24 Aug 2020 12:14:24

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'kg/m2'	System	31 Aug 2020 17:43:52
DataPoint set to visible.	System	24 Aug 2020 12:14:24

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered empty.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered empty.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'bpm'	System	31 Aug 2020 17:43:52



**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'breaths/min'	System	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'mmHg'	System	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:10
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'mmHg'	System	31 Aug 2020 17:43:52

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23

**US3412300**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23



US3412300

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:34:54
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	28 Sep 2020 20:42:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:42:49
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	31 Aug 2020 17:44:53
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:44:53

**US3412300**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:34:54
User entered '24 Aug 2020'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:44:53

US3412300

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:37:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:36:10
User entered '24 Aug 2020'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:45:41

**US3412300**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:36:10
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:45:41

**US3412300**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:37:03**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 06:29:16
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:36:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:36:10
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).		08 Oct 2020 05:52:03
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:45:41

**US3412300**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:37:03**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:36:10
User entered empty.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:45:41

**US3412300**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:37:03**

**If Surgically sterile, date of surgery (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:36:10
User entered empty.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:45:41

**US3412300**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:37:03**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:36:10
User entered '0'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:45:41



**US3412300**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:37:03**

*If Post-menopausal, date of last menstruation (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:36:10
User entered 'un UNK 2010'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:45:41

**US3412300**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:37:03**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:36:10
User entered '0'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:45:41

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25



US3412300

Folder: Screening

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**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

**US3412300**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:37:03**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 20:47:04
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered (b) (6) OPERATIONS SUPPORT STAFF SEES NUMEROUS PEOPLE (20 OR MORE A DAY.' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:47:04
User entered empty.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

**US3412300**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:37:03**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
User entered '0'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25



**US3412300**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:37:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered '0'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered '0'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered '0'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered '0'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User entered 'I'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	28 Sep 2020 20:47:20
User entered '0'	(b) (4)	
	Mylene Asmar-Rios	31 Aug 2020 17:49:25
	(b) (4)	

US3412300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:37:19
User closed query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	28 Sep 2020 20:47:20
User opened query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	28 Sep 2020 20:47:04
User entered 'LIVES IN HIGH RISK COUNTY. SOCIALIZES WITH FRIENDS AND FAMILY OFTEN' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:47:04
User entered empty.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:49:25

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:17
User entered 'Yes (Y)'		24 Aug 2020 12:12:57



**US3412300**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:17
User entered '24 Aug 2020'		24 Aug 2020 12:12:57

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:17
User entered 'Clinic (Clinic)'		24 Aug 2020 12:12:57

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'VISIT1'	System	24 Aug 2020 12:12:57

US3412300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:30
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 12:14:34

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:37:03**

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:30
User entered '144385'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 12:14:34

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:37:03**

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:30
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 12:14:34

US3412300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:37:03

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)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 06:29:33
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	09 Oct 2020 13:42:28
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:30
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Sep 2020 20:49:46
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:14:28

US3412300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:37:03

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)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:30
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:49:46



**US3412300**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:37:03**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:30
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:49:46

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:37:03**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:30
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:49:46

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:37:03**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:30
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:49:46

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:37:03**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:38:30
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Sep 2020 20:49:46
Amendment Manager: DataPoint set to visible.	(b) (4)	
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 10:39:36
	System	19 Sep 2020 02:24:00

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:37:03**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:37:03**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:37:03**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:37:03**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51



US3412300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User accepted default value 'Pre-Dose (PREDOSE)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

US3412300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '24 Aug 2020'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '7:55'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '24 Aug 2020 7:55'	System	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '36.8' C reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 20:51:32
User entered '98.2' F	(b) (4) Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered empty.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51



**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '88'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'bpm'	System	31 Aug 2020 17:51:51

US3412300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '18'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'breaths/min'	System	31 Aug 2020 17:51:51

US3412300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '134'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

US3412300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'mmHg'	System	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '78'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'mmHg'	System	31 Aug 2020 17:51:51



**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:37:03**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:37:03**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User accepted default value 'Post-Dose (POSTDOSE)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '24 Aug 2020'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '8:55'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '24 Aug 2020 8:55'	System	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '97.7' F	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51



**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered empty.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '66'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'bpm'	System	31 Aug 2020 17:51:51

US3412300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '16'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'breaths/min'	System	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '140'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'mmHg'	System	31 Aug 2020 17:51:51



**US3412300**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:43
User entered '80'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:51

US3412300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'mmHg'	System	31 Aug 2020 17:51:51

US3412300

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:51
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 20:51:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 20:51:42
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:51:42
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 17:51:58
User entered empty.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:58

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:00:51
User entered empty.	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:51:58

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:10:19
User entered 'Yes (Y)'		24 Aug 2020 12:26:10

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:10:19
User entered empty.		24 Aug 2020 12:26:10

US3412300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:03

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)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:10:19
User entered empty.		24 Aug 2020 12:26:10

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 12:26:10



**US3412300**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:10:19
User entered '24 Aug 2020'		24 Aug 2020 12:26:10

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:10:19
User entered '08:20'		24 Aug 2020 12:26:10

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '24 Aug 2020 08:20'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4)	08 Oct 2020 16:10:19
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	24 Aug 2020 12:26:10

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
DataPoint Verified.		08 Oct 2020 16:10:19
User entered 'ONCE'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:10:26
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:52:38

US3412300

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:10:26
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Sep 2020 20:53:19
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		28 Sep 2020 20:53:19
User entered '24 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:53:19
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Sep 2020 20:52:38
User entered '24 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:52:38



**US3412300**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:10:26
User entered '08:04'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:52:38

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '24 Aug 2020 08:04'	System	28 Sep 2020 20:53:19
User entered '24 Sep 2020 08:04'	System	28 Sep 2020 20:52:38

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:37:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:10:34
User entered '24 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:53:48

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:53:48

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:10:34
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:53:48

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:10:34
User entered '08:09'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:53:48

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '24 Aug 2020 08:09'	System	28 Sep 2020 20:53:48

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:53:48



**US3412300**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:10:34
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:53:48

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:10:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:53:48

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered empty.	System	28 Sep 2020 20:53:48

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:10:39
User entered 'Yes (Y)'		31 Aug 2020 16:58:16

**US3412300**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'I'	System	31 Aug 2020 16:58:16

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:52:25', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbe99856-013e-413c-896b-497297fe38aa'	System	24 Aug 2020 12:53:44
User entered 'Yes (Y)'	System	24 Aug 2020 12:53:44

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:53:26', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbe99856-013e-413c-896b-497297fe38aa' User entered '97.7'	System	24 Aug 2020 12:53:44
	System	24 Aug 2020 12:53:44



US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:53:31', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbe99856-013e-413c-896b-497297fe38aa' User entered 'No (N)'	System	24 Aug 2020 12:53:44
	System	24 Aug 2020 12:53:44

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:53:42', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbe99856-013e-413c-896b-497297fe38aa' User entered '24 Aug 2020 08:53'	System	24 Aug 2020 12:53:44
	System	24 Aug 2020 12:53:44

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Aug 2020 08:40'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Aug 2020 11:10'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:06:52', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '547253a2-8cd2-4430-a80b-b7fdb7fda1a' User entered 'Yes (Y)'	System	24 Aug 2020 22:07:31
	System	24 Aug 2020 22:07:31

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:07:18', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '547253a2-8cd2-4430-a80b-b7fdb7fda1a' User entered '97.9'	System	24 Aug 2020 22:07:31
	System	24 Aug 2020 22:07:31

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:07:21', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '547253a2-8cd2-4430-a80b-b7fdb7fda1a' User entered 'No (N)'	System	24 Aug 2020 22:07:31
	System	24 Aug 2020 22:07:31



**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:07:29', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '547253a2-8cd2-4430-a80b-b7fdb7fda1a' User entered '24 Aug 2020 18:07'	System	24 Aug 2020 22:07:31
	System	24 Aug 2020 22:07:31

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Aug 2020 12:05'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 2'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:29:26', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '12f308c3-9679-410b-8dcd-a544b4d1183d'	System	25 Aug 2020 17:29:43
User entered 'Yes (Y)'	System	25 Aug 2020 17:29:43

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:29:30', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '12f308c3-9679-410b-8dcd-a544b4d1183d'	System	25 Aug 2020 17:29:43
User entered '98.5'	System	25 Aug 2020 17:29:43

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:29:33', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '12f308c3-9679-410b-8dcd-a544b4d1183d'	System	25 Aug 2020 17:29:43
User entered 'No (N)'	System	25 Aug 2020 17:29:43

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:29:37', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '12f308c3-9679-410b-8dcd-a544b4d1183d' User entered '25 Aug 2020 13:29'	System	25 Aug 2020 17:29:43
	System	25 Aug 2020 17:29:43



US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 3'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:17', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e0cea1fc-dc6d-45c1-a784-33f880bc66'	System	26 Aug 2020 18:08:37
User entered 'Yes (Y)'	System	26 Aug 2020 18:08:37

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:23', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e0cea1fc-dc6d-45c1-a784-33f880bc66'	System	26 Aug 2020 18:08:37
User entered '97.6'	System	26 Aug 2020 18:08:37

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:26', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e0cea1fc-dc6d-45c1-a784-33f880bc66'	System	26 Aug 2020 18:08:37
User entered 'No (N)'	System	26 Aug 2020 18:08:37

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:33', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e0cea1fc-dc6d-45c1-a784-33f880bc66'	System	26 Aug 2020 18:08:37
User entered '26 Aug 2020 14:08'	System	26 Aug 2020 18:08:37

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 12:26:10



**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 4'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:41:37', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e4b1b2ec-11d5-419d-b6d8-aea7cde51bd5' User entered 'Yes (Y)'	System	27 Aug 2020 20:41:53
	System	27 Aug 2020 20:41:53

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:41:42', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e4b1b2ec-11d5-419d-b6d8-aea7cde51bd5' User entered '98.2'	System	27 Aug 2020 20:41:53
	System	27 Aug 2020 20:41:53

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:41:46', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e4b1b2ec-11d5-419d-b6d8-aea7cde51bd5'	System	27 Aug 2020 20:41:53
User entered 'No (N)'	System	27 Aug 2020 20:41:53

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:41:51', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e4b1b2ec-11d5-419d-b6d8-aea7cde51bd5' User entered '27 Aug 2020 16:41'	System	27 Aug 2020 20:41:53
	System	27 Aug 2020 20:41:53

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 12:26:10



**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 5'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:00:57', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'fb9101e5-bd57-4129-b935-fadd93a29bef'	System	28 Aug 2020 16:02:59
User entered 'Yes (Y)'	System	28 Aug 2020 16:02:59

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:01:51', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'fb9101e5-bd57-4129-b935-fadd93a29bef' User entered '97.8'	System	28 Aug 2020 16:02:59
	System	28 Aug 2020 16:02:59

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:01:57', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'fb9101e5-bd57-4129-b935-fadd93a29bef'	System	28 Aug 2020 16:02:59
User entered 'No (N)'	System	28 Aug 2020 16:02:59

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:01', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'fb9101e5-bd57-4129-b935-fadd93a29bef'	System	28 Aug 2020 16:02:59
User entered '28 Aug 2020 12:02'	System	28 Aug 2020 16:02:59

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 6'	System	24 Aug 2020 12:26:10



US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:33:33', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '19f505f8-8d07-4c38-a470-43dab04b40d6' User entered 'Yes (Y)'	System	29 Aug 2020 22:34:21
	System	29 Aug 2020 22:34:21

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:07', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '19f505f8-8d07-4c38-a470-43dab04b40d6' User entered '98.4'	System	29 Aug 2020 22:34:21
	System	29 Aug 2020 22:34:21

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:10', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '19f505f8-8d07-4c38-a470-43dab04b40d6'	System	29 Aug 2020 22:34:21
User entered 'No (N)'	System	29 Aug 2020 22:34:21

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:16', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '19f505f8-8d07-4c38-a470-43dab04b40d6' User entered '29 Aug 2020 18:34'	System	29 Aug 2020 22:34:21
	System	29 Aug 2020 22:34:21

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 7'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:22', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1e6461ff-2cb6-444f-863d-012bcb1c92c2'	System	31 Aug 2020 01:58:37
User entered 'Yes (Y)'	System	31 Aug 2020 01:58:37



US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:27', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1e6461ff-2cb6-444f-863d-012bcb1c92c2'	System	31 Aug 2020 01:58:37
User entered '98.4'	System	31 Aug 2020 01:58:37

US3412300

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:30', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1e6461ff-2cb6-444f-863d-012bcb1c92c2'	System	31 Aug 2020 01:58:37
User entered 'No (N)'	System	31 Aug 2020 01:58:37

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:34', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1e6461ff-2cb6-444f-863d-012bcb1c92c2'	System	31 Aug 2020 01:58:37
User entered '30 Aug 2020 21:58'	System	31 Aug 2020 01:58:37

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:54:15', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '164e3419-ea05-46c9-b755-3c01c777ffb5'	System	24 Aug 2020 12:54:43
User entered 'None (1)'	System	24 Aug 2020 12:54:43

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:54:18', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '164e3419-ea05-46c9-b755-3c01c777ffb5'	System	24 Aug 2020 12:54:43
User entered 'No (N)'	System	24 Aug 2020 12:54:43



US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:54:21', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '164e3419-ea05-46c9-b755-3c01c777ffb5'	System	24 Aug 2020 12:54:43
User entered 'No (N)'	System	24 Aug 2020 12:54:43

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:54:35', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '164e3419-ea05-46c9-b755-3c01c777ffb5'	System	24 Aug 2020 12:54:43
User entered 'None (1)'	System	24 Aug 2020 12:54:43

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:54:41', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '164e3419-ea05-46c9-b755-3c01c777ffb5'	System	24 Aug 2020 12:54:43
User entered '24 Aug 2020 08:54'	System	24 Aug 2020 12:54:43

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Aug 2020 08:40'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Aug 2020 11:10'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:07:43', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a8b4ed95-0556-4dff-bfe0-166913a414eb' User entered 'None (1)'	System	24 Aug 2020 22:07:59
	System	24 Aug 2020 22:07:59

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:07:46', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a8b4ed95-0556-4dff-bfe0-166913a414eb' User entered 'No (N)'	System	24 Aug 2020 22:07:59
	System	24 Aug 2020 22:07:59



US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:07:48', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a8b4ed95-0556-4dff-bfe0-166913a414eb' User entered 'No (N)'	System	24 Aug 2020 22:07:59
	System	24 Aug 2020 22:07:59

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:07:52', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a8b4ed95-0556-4dff-bfe0-166913a414eb' User entered 'None (1)'	System	24 Aug 2020 22:07:59
	System	24 Aug 2020 22:07:59

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:07:57', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a8b4ed95-0556-4dff-bfe0-166913a414eb' User entered '24 Aug 2020 18:07'	System	24 Aug 2020 22:07:59
	System	24 Aug 2020 22:07:59

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Aug 2020 12:05'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 2'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:29:47', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '02894d2e-2c81-43a8-88c3-263bd7eebb32'	System	25 Aug 2020 17:30:02
User entered 'None (1)'	System	25 Aug 2020 17:30:02

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:29:50', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '02894d2e-2c81-43a8-88c3-263bd7eebb32' User entered 'No (N)'	System	25 Aug 2020 17:30:02
	System	25 Aug 2020 17:30:02



US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:29:52', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '02894d2e-2c81-43a8-88c3-263bd7eebb32'	System	25 Aug 2020 17:30:02
User entered 'No (N)'	System	25 Aug 2020 17:30:02

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:29:54', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '02894d2e-2c81-43a8-88c3-263bd7eebb32'	System	25 Aug 2020 17:30:02
User entered 'None (1)'	System	25 Aug 2020 17:30:02

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:29:58', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '02894d2e-2c81-43a8-88c3-263bd7eebb32'	System	25 Aug 2020 17:30:02
User entered '25 Aug 2020 13:29'	System	25 Aug 2020 17:30:02

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 3'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:38', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbb056f7-e4d2-4211-8bab-71f8fef4fef4'	System	26 Aug 2020 18:08:52
User entered 'None (1)'	System	26 Aug 2020 18:08:52

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:41', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbb056f7-e4d2-4211-8bab-71f8fef4fef4'	System	26 Aug 2020 18:08:52
User entered 'No (N)'	System	26 Aug 2020 18:08:52



US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:43', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbb056f7-e4d2-4211-8bab-71f8fef4fef4'	System	26 Aug 2020 18:08:52
User entered 'No (N)'	System	26 Aug 2020 18:08:52

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:44', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbb056f7-e4d2-4211-8bab-71f8fef4fef4' User entered 'None (1)'	System	26 Aug 2020 18:08:52
	System	26 Aug 2020 18:08:52

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:50', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbb056f7-e4d2-4211-8bab-71f8fef4fef4'	System	26 Aug 2020 18:08:52
User entered '26 Aug 2020 14:08'	System	26 Aug 2020 18:08:52

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 4'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:41:55', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '69b6a096-3b9e-48f7-8b08-39ee7d3488ca' User entered 'None (1)'	System	27 Aug 2020 20:42:21
	System	27 Aug 2020 20:42:21

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:41:58', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '69b6a096-3b9e-48f7-8b08-39ee7d3488ca' User entered 'No (N)'	System	27 Aug 2020 20:42:21
	System	27 Aug 2020 20:42:21



US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:42:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '69b6a096-3b9e-48f7-8b08-39ee7d3488ca' User entered 'No (N)'	System	27 Aug 2020 20:42:21
	System	27 Aug 2020 20:42:21

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:42:04', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '69b6a096-3b9e-48f7-8b08-39ee7d3488ca' User entered 'None (1)'	System	27 Aug 2020 20:42:21
	System	27 Aug 2020 20:42:21

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:42:19', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '69b6a096-3b9e-48f7-8b08-39ee7d3488ca' User entered '27 Aug 2020 16:42'	System	27 Aug 2020 20:42:21
	System	27 Aug 2020 20:42:21

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 5'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:04', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0ebd3393-1762-4289-98a7-32fdc8f760a3'	System	28 Aug 2020 16:03:20
User entered 'None (1)'	System	28 Aug 2020 16:03:20

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:07', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0ebd3393-1762-4289-98a7-32fdc8f760a3'	System	28 Aug 2020 16:03:20
User entered 'No (N)'	System	28 Aug 2020 16:03:20



US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:09', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0ebd3393-1762-4289-98a7-32fdc8f760a3'	System	28 Aug 2020 16:03:20
User entered 'No (N)'	System	28 Aug 2020 16:03:20

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:11', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0ebd3393-1762-4289-98a7-32fdc8f760a3' User entered 'None (1)'	System	28 Aug 2020 16:03:20
	System	28 Aug 2020 16:03:20

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:14', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0ebd3393-1762-4289-98a7-32fdc8f760a3'	System	28 Aug 2020 16:03:20
User entered '28 Aug 2020 12:02'	System	28 Aug 2020 16:03:20

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 6'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:19', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ded8e7be-4147-4b86-817c-bae7c726a90e' User entered 'None (1)'	System	29 Aug 2020 22:34:36
	System	29 Aug 2020 22:34:36

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:22', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ded8e7be-4147-4b86-817c-bae7c726a90e' User entered 'No (N)'	System	29 Aug 2020 22:34:36
	System	29 Aug 2020 22:34:36



US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:25', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ded8e7be-4147-4b86-817c-bae7c726a90e' User entered 'No (N)'	System	29 Aug 2020 22:34:36
	System	29 Aug 2020 22:34:36

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:27', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ded8e7be-4147-4b86-817c-bae7c726a90e' User entered 'None (1)'	System	29 Aug 2020 22:34:36
	System	29 Aug 2020 22:34:36

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:30', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ded8e7be-4147-4b86-817c-bae7c726a90e' User entered '29 Aug 2020 18:34'	System	29 Aug 2020 22:34:36
	System	29 Aug 2020 22:34:36

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 7'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:38', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '93998ff1-5953-439a-a0b6-cc9dac765fb2'	System	31 Aug 2020 01:58:49
User entered 'None (1)'	System	31 Aug 2020 01:58:49

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:40', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '93998ff1-5953-439a-a0b6-cc9dac765fb2'	System	31 Aug 2020 01:58:49
User entered 'No (N)'	System	31 Aug 2020 01:58:49



US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:42', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '93998ff1-5953-439a-a0b6-cc9dac765fb2'	System	31 Aug 2020 01:58:49
User entered 'No (N)'	System	31 Aug 2020 01:58:49

US3412300

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:43', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '93998ff1-5953-439a-a0b6-cc9dac765fb2'	System	31 Aug 2020 01:58:49
User entered 'None (1)'	System	31 Aug 2020 01:58:49

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:46', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '93998ff1-5953-439a-a0b6-cc9dac765fb2'	System	31 Aug 2020 01:58:49
User entered '30 Aug 2020 21:58'	System	31 Aug 2020 01:58:49

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:54:53', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10b69807-4ea9-4973-8fe5-910757559325' User entered 'None (0)'	System	24 Aug 2020 12:55:20
	System	24 Aug 2020 12:55:20

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:54:59', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10b69807-4ea9-4973-8fe5-910757559325'	System	24 Aug 2020 12:55:20
User entered 'None (0)'	System	24 Aug 2020 12:55:20



US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:55:02', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10b69807-4ea9-4973-8fe5-910757559325'	System	24 Aug 2020 12:55:20
User entered 'None (0)'	System	24 Aug 2020 12:55:20

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:55:05', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10b69807-4ea9-4973-8fe5-910757559325' User entered 'None (0)'	System	24 Aug 2020 12:55:20
	System	24 Aug 2020 12:55:20

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:55:08', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10b69807-4ea9-4973-8fe5-910757559325' User entered 'None (0)'	System	24 Aug 2020 12:55:20
	System	24 Aug 2020 12:55:20

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:55:10', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10b69807-4ea9-4973-8fe5-910757559325'	System	24 Aug 2020 12:55:20
User entered 'None (0)'	System	24 Aug 2020 12:55:20

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:55:13', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10b69807-4ea9-4973-8fe5-910757559325'	System	24 Aug 2020 12:55:20
User entered 'No (N)'	System	24 Aug 2020 12:55:20

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T08:55:18', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10b69807-4ea9-4973-8fe5-910757559325'	System	24 Aug 2020 12:55:20
User entered '24 Aug 2020 08:55'	System	24 Aug 2020 12:55:20

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Aug 2020 08:40'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Aug 2020 11:10'	System	24 Aug 2020 12:26:10



**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:08:03', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6fc86fee-35b5-4c6f-a7fe-b60e771a9007'	System	24 Aug 2020 22:08:23
User entered 'None (0)'	System	24 Aug 2020 22:08:23

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:08:06', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6fc86fee-35b5-4c6f-a7fe-b60e771a9007'	System	24 Aug 2020 22:08:23
User entered 'None (0)'	System	24 Aug 2020 22:08:23

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:08:08', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6fc86fee-35b5-4c6f-a7fe-b60e771a9007'	System	24 Aug 2020 22:08:23
User entered 'None (0)'	System	24 Aug 2020 22:08:23

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:08:09', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6fc86fee-35b5-4c6f-a7fe-b60e771a9007'	System	24 Aug 2020 22:08:23
User entered 'None (0)'	System	24 Aug 2020 22:08:23

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:08:11', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6fc86fee-35b5-4c6f-a7fe-b60e771a9007'	System	24 Aug 2020 22:08:23
User entered 'None (0)'	System	24 Aug 2020 22:08:23

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:08:13', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6fc86fee-35b5-4c6f-a7fe-b60e771a9007'	System	24 Aug 2020 22:08:23
User entered 'None (0)'	System	24 Aug 2020 22:08:23

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:08:16', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6fc86fee-35b5-4c6f-a7fe-b60e771a9007'	System	24 Aug 2020 22:08:23
User entered 'No (N)'	System	24 Aug 2020 22:08:23



**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-24T18:08:19', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6fc86fee-35b5-4c6f-a7fe-b60e771a9007'	System	24 Aug 2020 22:08:23
User entered '24 Aug 2020 18:08'	System	24 Aug 2020 22:08:23

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Aug 2020 12:05'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 2'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:30:01', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'b55f5ec1-fafa-4662-b403-08cc29f60c73'	System	25 Aug 2020 17:30:18
User entered 'None (0)'	System	25 Aug 2020 17:30:18

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:30:04', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'b55f5ec1-fafa-4662-b403-08cc29f60c73'	System	25 Aug 2020 17:30:18
User entered 'None (0)'	System	25 Aug 2020 17:30:18

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:30:05', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'b55f5ec1-fafa-4662-b403-08cc29f60c73' User entered 'None (0)'	System	25 Aug 2020 17:30:18
	System	25 Aug 2020 17:30:18

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:30:06', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'b55f5ec1-fafa-4662-b403-08cc29f60c73' User entered 'None (0)'	System	25 Aug 2020 17:30:18
	System	25 Aug 2020 17:30:18



US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:30:08', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'b55f5ec1-fafa-4662-b403-08cc29f60c73'	System	25 Aug 2020 17:30:18
User entered 'None (0)'	System	25 Aug 2020 17:30:18

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:30:10', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'b55f5ec1-fafa-4662-b403-08cc29f60c73' User entered 'None (0)'	System	25 Aug 2020 17:30:18
	System	25 Aug 2020 17:30:18

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:30:12', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'b55f5ec1-fafa-4662-b403-08cc29f60c73'	System	25 Aug 2020 17:30:18
User entered 'No (N)'	System	25 Aug 2020 17:30:18

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-25T13:30:16', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'b55f5ec1-fafa-4662-b403-08cc29f60c73'	System	25 Aug 2020 17:30:18
User entered '25 Aug 2020 13:30'	System	25 Aug 2020 17:30:18

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 3'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:54', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0dd13aec-5a99-49c0-97b2-63d28568effb' User entered 'None (0)'	System	26 Aug 2020 18:09:13
	System	26 Aug 2020 18:09:13



**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:57', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0dd13aec-5a99-49c0-97b2-63d28568effb' User entered 'None (0)'	System	26 Aug 2020 18:09:13
	System	26 Aug 2020 18:09:13

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:08:59', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0dd13aec-5a99-49c0-97b2-63d28568effb' User entered 'None (0)'	System	26 Aug 2020 18:09:13
	System	26 Aug 2020 18:09:13

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:09:01', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0dd13aec-5a99-49c0-97b2-63d28568effb' User entered 'None (0)'	System	26 Aug 2020 18:09:13
	System	26 Aug 2020 18:09:13

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:09:02', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0dd13aec-5a99-49c0-97b2-63d28568effb' User entered 'None (0)'	System	26 Aug 2020 18:09:13
	System	26 Aug 2020 18:09:13

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:09:04', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0dd13aec-5a99-49c0-97b2-63d28568effb' User entered 'None (0)'	System	26 Aug 2020 18:09:13
	System	26 Aug 2020 18:09:13

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:09:07', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0dd13aec-5a99-49c0-97b2-63d28568effb' User entered 'No (N)'	System	26 Aug 2020 18:09:13
	System	26 Aug 2020 18:09:13

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-26T14:09:10', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0dd13aec-5a99-49c0-97b2-63d28568effb' User entered '26 Aug 2020 14:09'	System	26 Aug 2020 18:09:13
	System	26 Aug 2020 18:09:13

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 12:26:10



**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 4'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:42:27', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '76d49246-f7e9-449e-bce3-3f33a8aaf027'	System	27 Aug 2020 20:43:39
User entered 'None (0)'	System	27 Aug 2020 20:43:39

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:42:43', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '76d49246-f7e9-449e-bce3-3f33a8aaf027'	System	27 Aug 2020 20:43:39
User entered 'None (0)'	System	27 Aug 2020 20:43:39

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:42:53', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '76d49246-f7e9-449e-bce3-3f33a8aaf027'	System	27 Aug 2020 20:43:39
User entered 'None (0)'	System	27 Aug 2020 20:43:39

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:43:25', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '76d49246-f7e9-449e-bce3-3f33a8aaf027'	System	27 Aug 2020 20:43:39
User entered 'None (0)'	System	27 Aug 2020 20:43:39

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:43:27', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '76d49246-f7e9-449e-bce3-3f33a8aaf027'	System	27 Aug 2020 20:43:39
User entered 'None (0)'	System	27 Aug 2020 20:43:39

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:43:29', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '76d49246-f7e9-449e-bce3-3f33a8aaf027'	System	27 Aug 2020 20:43:39
User entered 'None (0)'	System	27 Aug 2020 20:43:39



US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:43:31', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '76d49246-f7e9-449e-bce3-3f33a8aaf027'	System	27 Aug 2020 20:43:39
User entered 'No (N)'	System	27 Aug 2020 20:43:39

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-27T16:43:37', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '76d49246-f7e9-449e-bce3-3f33a8aaf027'	System	27 Aug 2020 20:43:39
User entered '27 Aug 2020 16:43'	System	27 Aug 2020 20:43:39

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 5'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:18', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42a14610-6aea-40f4-acb5-e9522244623c' User entered 'None (0)'	System	28 Aug 2020 16:03:47
	System	28 Aug 2020 16:03:47

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:19', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42a14610-6aea-40f4-acb5-e9522244623c' User entered 'None (0)'	System	28 Aug 2020 16:03:47
	System	28 Aug 2020 16:03:47

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:21', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42a14610-6aea-40f4-acb5-e9522244623c' User entered 'None (0)'	System	28 Aug 2020 16:03:47
	System	28 Aug 2020 16:03:47



US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:22', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42a14610-6aea-40f4-acb5-e9522244623c' User entered 'None (0)'	System	28 Aug 2020 16:03:47
	System	28 Aug 2020 16:03:47

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:24', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42a14610-6aea-40f4-acb5-e9522244623c' User entered 'None (0)'	System	28 Aug 2020 16:03:47
	System	28 Aug 2020 16:03:47

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:25', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42a14610-6aea-40f4-acb5-e9522244623c' User entered 'None (0)'	System	28 Aug 2020 16:03:47
	System	28 Aug 2020 16:03:47

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:28', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42a14610-6aea-40f4-acb5-e9522244623c' User entered 'No (N)'	System	28 Aug 2020 16:03:47
	System	28 Aug 2020 16:03:47

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-28T12:02:31', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42a14610-6aea-40f4-acb5-e9522244623c' User entered '28 Aug 2020 12:02'	System	28 Aug 2020 16:03:47
	System	28 Aug 2020 16:03:47

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 6'	System	24 Aug 2020 12:26:10



US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:34', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbbd3b7b-a5dc-4284-a76a-c6dadd82e309' User entered 'None (0)'	System	29 Aug 2020 22:34:49
	System	29 Aug 2020 22:34:49

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:35', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbbd3b7b-a5dc-4284-a76a-c6dadd82e309' User entered 'None (0)'	System	29 Aug 2020 22:34:49
	System	29 Aug 2020 22:34:49

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:37', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbbd3b7b-a5dc-4284-a76a-c6dadd82e309'	System	29 Aug 2020 22:34:49
User entered 'None (0)'	System	29 Aug 2020 22:34:49

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:38', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbbd3b7b-a5dc-4284-a76a-c6dadd82e309' User entered 'None (0)'	System	29 Aug 2020 22:34:49
	System	29 Aug 2020 22:34:49

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:40', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbbd3b7b-a5dc-4284-a76a-c6dadd82e309' User entered 'None (0)'	System	29 Aug 2020 22:34:49
	System	29 Aug 2020 22:34:49

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:41', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbbd3b7b-a5dc-4284-a76a-c6dadd82e309' User entered 'None (0)'	System	29 Aug 2020 22:34:49
	System	29 Aug 2020 22:34:49

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:44', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbbd3b7b-a5dc-4284-a76a-c6dadd82e309'	System	29 Aug 2020 22:34:49
User entered 'No (N)'	System	29 Aug 2020 22:34:49

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-29T18:34:47', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'bbbd3b7b-a5dc-4284-a76a-c6dadd82e309' User entered '29 Aug 2020 18:34'	System	29 Aug 2020 22:34:49
	System	29 Aug 2020 22:34:49



**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 7'	System	24 Aug 2020 12:26:10

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:49', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ba1b9fa6-4491-4f7c-a018-37cf6e4cb934'	System	31 Aug 2020 01:59:06
User entered 'None (0)'	System	31 Aug 2020 01:59:06

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:52', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ba1b9fa6-4491-4f7c-a018-37cf6e4cb934'	System	31 Aug 2020 01:59:06
User entered 'None (0)'	System	31 Aug 2020 01:59:06

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:54', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ba1b9fa6-4491-4f7c-a018-37cf6e4cb934'	System	31 Aug 2020 01:59:06
User entered 'None (0)'	System	31 Aug 2020 01:59:06

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:55', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ba1b9fa6-4491-4f7c-a018-37cf6e4cb934'	System	31 Aug 2020 01:59:06
User entered 'None (0)'	System	31 Aug 2020 01:59:06

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:57', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ba1b9fa6-4491-4f7c-a018-37cf6e4cb934'	System	31 Aug 2020 01:59:06
User entered 'None (0)'	System	31 Aug 2020 01:59:06



US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:58:58', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ba1b9fa6-4491-4f7c-a018-37cf6e4cb934'	System	31 Aug 2020 01:59:06
User entered 'None (0)'	System	31 Aug 2020 01:59:06

US3412300

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:59:02', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ba1b9fa6-4491-4f7c-a018-37cf6e4cb934'	System	31 Aug 2020 01:59:06
User entered 'No (N)'	System	31 Aug 2020 01:59:06

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-08-30T21:59:04', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ba1b9fa6-4491-4f7c-a018-37cf6e4cb934'	System	31 Aug 2020 01:59:06
User entered '30 Aug 2020 21:59'	System	31 Aug 2020 01:59:06

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 12:26:10

**US3412300**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:11:53
User entered 'Yes (Y)'		31 Aug 2020 17:23:41

**US3412300**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:11:53
User entered '31 Aug 2020'		31 Aug 2020 17:23:41

**US3412300**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:11:53
User entered 'Contact Made (CONTACT MADE)'		31 Aug 2020 17:23:41



**US3412300**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:11:53
User entered empty.		31 Aug 2020 17:23:41

**US3412300**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:11:57
User entered 'Yes (Y)'		31 Aug 2020 17:23:53

**US3412300**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'I'	System	31 Aug 2020 17:23:53

**US3412300**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:12:15
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	08 Sep 2020 15:22:04

**US3412300**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:12:15
User entered '8 Sep 2020'	Mason Urban (b) (4) (b) (4)	08 Sep 2020 15:22:04

**US3412300**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:12:15
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	08 Sep 2020 15:22:04

**US3412300**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:12:15
User entered empty.	Mason Urban (b) (4) (b) (4)	08 Sep 2020 15:22:04

**US3412300**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:12:20
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	08 Sep 2020 15:22:13



**US3412300**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'I'	System	08 Sep 2020 15:22:13

**US3412300**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:12:34
User entered 'Yes (Y)'		14 Sep 2020 12:46:34

**US3412300**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:34
User entered '14 Sep 2020'		14 Sep 2020 12:46:34

**US3412300**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:34
User entered 'Contact Made (CONTACT MADE)'		14 Sep 2020 12:46:34

**US3412300**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:34
User entered empty.		14 Sep 2020 12:46:34

**US3412300**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:38
User entered 'Yes (Y)'		14 Sep 2020 12:48:01

**US3412300**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'I'	System	14 Sep 2020 12:48:01

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:43
User entered 'Yes (Y)'		21 Sep 2020 13:17:41



**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:43
User entered '21 Sep 2020'		21 Sep 2020 13:17:41

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:43
User entered 'Clinic (Clinic)'		21 Sep 2020 13:17:41

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'VISIT2'	System	21 Sep 2020 13:17:41

US3412300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User accepted default value 'Pre-Dose (PREDOSE)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '21 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '08:15'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '21 Sep 2020 08:15'	System	28 Sep 2020 20:57:52



US3412300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '36.4' C	Melissa Fuson (b) (4)	28 Sep 2020 20:57:52

US3412300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '76'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'bpm'	System	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '16'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'breaths/min'	System	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '114'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52



**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'mmHg'	System	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '84'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'mmHg'	System	28 Sep 2020 20:57:52

US3412300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User accepted default value 'Post-Dose (POSTDOSE)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '21 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '09:50'	Melissa Fuson (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '21 Sep 2020 09:50'	System	28 Sep 2020 20:57:52



US3412300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '97.5' F	Melissa Fuson (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '74'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'bpm'	System	28 Sep 2020 20:57:52

US3412300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '16'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

US3412300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'breaths/min'	System	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '120'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52



**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'mmHg'	System	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:36
User entered '80'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:57:52

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'mmHg'	System	28 Sep 2020 20:57:52

US3412300

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:13:26
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 20:58:25

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:13:26
User entered '21 Sep 2020'	Melissa Fuson (b) (4)	28 Sep 2020 20:58:25

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:14:58
User entered 'Yes (Y)'		21 Sep 2020 13:19:30

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:14:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 13:19:30

US3412300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:03

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)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:14:58
User entered empty.		21 Sep 2020 13:19:30



**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4)	08 Oct 2020 16:14:58
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 13:19:30

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4)	08 Oct 2020 16:14:58
User entered '09:15'	(b) (4), (b) (6)	21 Sep 2020 13:19:30

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '21 Sep 2020 09:15'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:14:58
User entered 'Left Arm (LEFT ARM)'		21 Sep 2020 13:19:30

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
DataPoint Verified.		08 Oct 2020 16:14:58
User entered 'ONCE'	System	21 Sep 2020 13:19:30

US3412300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 13:19:30

US3412300

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:15:10
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 21:00:11



**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:15:10
User entered '21 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 21:00:11

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:15:10
User entered '08:38'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 21:00:11

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '21 Sep 2020 08:38'	System	28 Sep 2020 21:00:11

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:15:15
User entered '21 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 21:00:34

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 21:00:34

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:15:15
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 21:00:34

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:15:15
User entered '08:33'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 21:00:34

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '21 Sep 2020 08:33'	System	28 Sep 2020 21:00:34



**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 21:00:34

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:15:15
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 21:00:34

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:15:15
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 21:00:34

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered empty.	System	28 Sep 2020 21:00:34

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4)	08 Oct 2020 16:15:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:00:13

**US3412300**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'I'	System	28 Sep 2020 20:00:13

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:50:29', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6f3db930-7149-4c88-a0e1-283fec739080' User entered 'Yes (Y)'	System	21 Sep 2020 13:50:49
	System	21 Sep 2020 13:50:49



US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:50:34', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6f3db930-7149-4c88-a0e1-283fec739080' User entered '97.5'	System	21 Sep 2020 13:50:49
	System	21 Sep 2020 13:50:49

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:50:38', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6f3db930-7149-4c88-a0e1-283fec739080' User entered 'No (N)'	System	21 Sep 2020 13:50:49
	System	21 Sep 2020 13:50:49

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:50:44', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6f3db930-7149-4c88-a0e1-283fec739080'	System	21 Sep 2020 13:50:49
User entered '21 Sep 2020 09:50'	System	21 Sep 2020 13:50:49

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '21 Sep 2020 09:35'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '21 Sep 2020 12:05'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:21:33', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '72adc25f-22f1-4da8-b192-994c50fad02e' User entered 'Yes (Y)'	System	21 Sep 2020 22:22:01
	System	21 Sep 2020 22:22:01

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:21:50', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '72adc25f-22f1-4da8-b192-994c50fad02e' User entered '97.9'	System	21 Sep 2020 22:22:01
	System	21 Sep 2020 22:22:01



US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:21:52', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '72adc25f-22f1-4da8-b192-994c50fad02e' User entered 'No (N)'	System	21 Sep 2020 22:22:01
	System	21 Sep 2020 22:22:01

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:21:57', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '72adc25f-22f1-4da8-b192-994c50fad02e' User entered '21 Sep 2020 18:21'	System	21 Sep 2020 22:22:01
	System	21 Sep 2020 22:22:01

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '21 Sep 2020 13:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 2'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:04:55', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a000a66a-e616-40ed-aeaf-c8e9c17492f8' User entered 'Yes (Y)'	System	22 Sep 2020 21:05:12
	System	22 Sep 2020 21:05:12

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:04:59', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a000a66a-e616-40ed-aeaf-c8e9c17492f8'	System	22 Sep 2020 21:05:12
User entered '98.5'	System	22 Sep 2020 21:05:12

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:03', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a000a66a-e616-40ed-aeaf-c8e9c17492f8'	System	22 Sep 2020 21:05:12
User entered 'No (N)'	System	22 Sep 2020 21:05:12



**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:07', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a000a66a-e616-40ed-aeaf-c8e9c17492f8'	System	22 Sep 2020 21:05:12
User entered '22 Sep 2020 17:05'	System	22 Sep 2020 21:05:12

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 3'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:13:41', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '414965a8-0586-4414-9274-40a458b0d547'	System	23 Sep 2020 20:14:07
User entered 'Yes (Y)'	System	23 Sep 2020 20:14:07

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:13:56', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '414965a8-0586-4414-9274-40a458b0d547'	System	23 Sep 2020 20:14:07
User entered '98.3'	System	23 Sep 2020 20:14:07

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:13:59', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '414965a8-0586-4414-9274-40a458b0d547'	System	23 Sep 2020 20:14:07
User entered 'No (N)'	System	23 Sep 2020 20:14:07

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:04', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '414965a8-0586-4414-9274-40a458b0d547'	System	23 Sep 2020 20:14:07
User entered '23 Sep 2020 16:14'	System	23 Sep 2020 20:14:07



**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 4'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T19:13:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '11faca7d-82af-4349-bc62-67930d8059b5' User entered 'Yes (Y)'	System	24 Sep 2020 23:13:21
	System	24 Sep 2020 23:13:21

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T19:13:05', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '11faca7d-82af-4349-bc62-67930d8059b5' User entered '96.5'	System	24 Sep 2020 23:13:21
	System	24 Sep 2020 23:13:21

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T19:13:10', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '11faca7d-82af-4349-bc62-67930d8059b5' User entered 'No (N)'	System	24 Sep 2020 23:13:21
	System	24 Sep 2020 23:13:21

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T19:13:18', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '11faca7d-82af-4349-bc62-67930d8059b5' User entered '24 Sep 2020 19:13'	System	24 Sep 2020 23:13:21
	System	24 Sep 2020 23:13:21

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:19:30



**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 5'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:56:26', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'c1e521ff-a74e-4247-87c2-26ed2567b6e6' User entered 'Yes (Y)'	System	25 Sep 2020 22:56:43
	System	25 Sep 2020 22:56:43

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:56:31', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'c1e521ff-a74e-4247-87c2-26ed2567b6e6'	System	25 Sep 2020 22:56:43
User entered '97.8'	System	25 Sep 2020 22:56:43

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:56:34', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'c1e521ff-a74e-4247-87c2-26ed2567b6e6' User entered 'No (N)'	System	25 Sep 2020 22:56:43
	System	25 Sep 2020 22:56:43

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:56:41', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'c1e521ff-a74e-4247-87c2-26ed2567b6e6'	System	25 Sep 2020 22:56:43
User entered '25 Sep 2020 18:56'	System	25 Sep 2020 22:56:43

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:19:30



US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 6'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:46:20', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '48cdff20-9bcc-4013-addc-bec2e14a611b' User entered 'Yes (Y)'	System	26 Sep 2020 23:46:48
	System	26 Sep 2020 23:46:48

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:46:35', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '48cdff20-9bcc-4013-addc-bec2e14a611b' User entered '97.2'	System	26 Sep 2020 23:46:48
	System	26 Sep 2020 23:46:48

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:46:39', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '48cdff20-9bcc-4013-addc-bec2e14a611b' User entered 'No (N)'	System	26 Sep 2020 23:46:48
	System	26 Sep 2020 23:46:48

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:46:45', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '48cdff20-9bcc-4013-addc-bec2e14a611b' User entered '26 Sep 2020 19:46'	System	26 Sep 2020 23:46:48
	System	26 Sep 2020 23:46:48

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 7'	System	21 Sep 2020 13:19:30



US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '52cfc35a-6e8f-4109-9ef0-43629f4c3d50'	System	28 Sep 2020 01:08:16
User entered 'Yes (Y)'	System	28 Sep 2020 01:08:16

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:04', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '52cfc35a-6e8f-4109-9ef0-43629f4c3d50' User entered '97.7'	System	28 Sep 2020 01:08:16
	System	28 Sep 2020 01:08:16

US3412300

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:07', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '52cfc35a-6e8f-4109-9ef0-43629f4c3d50'	System	28 Sep 2020 01:08:16
User entered 'No (N)'	System	28 Sep 2020 01:08:16

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:13', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '52cfc35a-6e8f-4109-9ef0-43629f4c3d50'	System	28 Sep 2020 01:08:16
User entered '27 Sep 2020 21:08'	System	28 Sep 2020 01:08:16

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:50:49', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8bcc8ede-0648-47a4-8053-67fb20d6e43b' User entered 'None (1)'	System	21 Sep 2020 13:51:09
	System	21 Sep 2020 13:51:09



US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:50:52', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8bcc8ede-0648-47a4-8053-67fb20d6e43b' User entered 'No (N)'	System	21 Sep 2020 13:51:09
	System	21 Sep 2020 13:51:09

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:50:54', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8bcc8ede-0648-47a4-8053-67fb20d6e43b' User entered 'No (N)'	System	21 Sep 2020 13:51:09
	System	21 Sep 2020 13:51:09

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:51:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8bcc8ede-0648-47a4-8053-67fb20d6e43b' User entered 'None (1)'	System	21 Sep 2020 13:51:09
	System	21 Sep 2020 13:51:09

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:51:04', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8bcc8ede-0648-47a4-8053-67fb20d6e43b'	System	21 Sep 2020 13:51:09
User entered '21 Sep 2020 09:51'	System	21 Sep 2020 13:51:09

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '21 Sep 2020 09:35'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '21 Sep 2020 12:05'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:08', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '992aed04-2381-49ed-8cdd-7221e0fdf19b' User entered 'None (1)'	System	21 Sep 2020 22:22:24
	System	21 Sep 2020 22:22:24



US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:11', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '992aed04-2381-49ed-8cdd-7221e0fdf19b' User entered 'No (N)'	System	21 Sep 2020 22:22:24
	System	21 Sep 2020 22:22:24

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:14', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '992aed04-2381-49ed-8cdd-7221e0fdf19b' User entered 'No (N)'	System	21 Sep 2020 22:22:24
	System	21 Sep 2020 22:22:24

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:16', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '992aed04-2381-49ed-8cdd-7221e0fdf19b' User entered 'None (1)'	System	21 Sep 2020 22:22:24
	System	21 Sep 2020 22:22:24

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:22', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '992aed04-2381-49ed-8cdd-7221e0fdf19b'	System	21 Sep 2020 22:22:24
User entered '21 Sep 2020 18:22'	System	21 Sep 2020 22:22:24

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '21 Sep 2020 13:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 2'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:11', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a6f5c825-587d-4aa9-b8a1-fe323c30452f' User entered 'None (1)'	System	22 Sep 2020 21:05:22
	System	22 Sep 2020 21:05:22



US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:13', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a6f5c825-587d-4aa9-b8a1-fe323c30452f' User entered 'No (N)'	System	22 Sep 2020 21:05:22
	System	22 Sep 2020 21:05:22

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:15', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a6f5c825-587d-4aa9-b8a1-fe323c30452f' User entered 'No (N)'	System	22 Sep 2020 21:05:22
	System	22 Sep 2020 21:05:22

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:16', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a6f5c825-587d-4aa9-b8a1-fe323c30452f' User entered 'None (1)'	System	22 Sep 2020 21:05:22
	System	22 Sep 2020 21:05:22

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:20', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a6f5c825-587d-4aa9-b8a1-fe323c30452f' User entered '22 Sep 2020 17:05'	System	22 Sep 2020 21:05:22
	System	22 Sep 2020 21:05:22

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 3'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:09', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42b7106c-0707-4aa4-9c03-06fe748e2148' User entered 'None (1)'	System	23 Sep 2020 20:14:25
	System	23 Sep 2020 20:14:25



US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:12', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42b7106c-0707-4aa4-9c03-06fe748e2148' User entered 'No (N)'	System	23 Sep 2020 20:14:25
	System	23 Sep 2020 20:14:25

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:14', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42b7106c-0707-4aa4-9c03-06fe748e2148' User entered 'No (N)'	System	23 Sep 2020 20:14:25
	System	23 Sep 2020 20:14:25

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:16', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42b7106c-0707-4aa4-9c03-06fe748e2148' User entered 'None (1)'	System	23 Sep 2020 20:14:25
	System	23 Sep 2020 20:14:25

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:20', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '42b7106c-0707-4aa4-9c03-06fe748e2148'	System	23 Sep 2020 20:14:25
User entered '23 Sep 2020 16:14'	System	23 Sep 2020 20:14:25

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 4'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '36d9e6d1-fb00-4fbf-9df0-42ce7e04e7be'	System	24 Sep 2020 18:07:12
User entered 'None (1)'	System	24 Sep 2020 18:07:12



US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:03', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '36d9e6d1-fb00-4fbf-9df0-42ce7e04e7be' User entered 'No (N)'	System	24 Sep 2020 18:07:12
	System	24 Sep 2020 18:07:12

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:05', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '36d9e6d1-fb00-4fbf-9df0-42ce7e04e7be' User entered 'No (N)'	System	24 Sep 2020 18:07:12
	System	24 Sep 2020 18:07:12

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:06', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '36d9e6d1-fb00-4fbf-9df0-42ce7e04e7be' User entered 'None (1)'	System	24 Sep 2020 18:07:12
	System	24 Sep 2020 18:07:12

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:11', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '36d9e6d1-fb00-4fbf-9df0-42ce7e04e7be'	System	24 Sep 2020 18:07:12
User entered '24 Sep 2020 14:07'	System	24 Sep 2020 18:07:12

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 5'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:56:44', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '501af945-b098-463c-afdf-409e6e5666f7'	System	25 Sep 2020 22:57:04
User entered 'None (1)'	System	25 Sep 2020 22:57:04



US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:56:47', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '501af945-b098-463c-afdf-409e6e5666f7' User entered 'No (N)'	System	25 Sep 2020 22:57:04
	System	25 Sep 2020 22:57:04

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:56:48', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '501af945-b098-463c-afdf-409e6e5666f7' User entered 'No (N)'	System	25 Sep 2020 22:57:04
	System	25 Sep 2020 22:57:04

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:56:51', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '501af945-b098-463c-afdf-409e6e5666f7' User entered 'None (1)'	System	25 Sep 2020 22:57:04
	System	25 Sep 2020 22:57:04

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:57:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '501af945-b098-463c-afdf-409e6e5666f7' User entered '25 Sep 2020 18:57'	System	25 Sep 2020 22:57:04
	System	25 Sep 2020 22:57:04

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 6'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:46:47', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0176f49e-37ff-4a61-8a50-ca96c1bb84ac'	System	26 Sep 2020 23:46:59
User entered 'None (1)'	System	26 Sep 2020 23:46:59



US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:46:50', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0176f49e-37ff-4a61-8a50-ca96c1bb84ac' User entered 'No (N)'	System	26 Sep 2020 23:46:59
	System	26 Sep 2020 23:46:59

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:46:53', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0176f49e-37ff-4a61-8a50-ca96c1bb84ac'	System	26 Sep 2020 23:46:59
User entered 'No (N)'	System	26 Sep 2020 23:46:59

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:46:54', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0176f49e-37ff-4a61-8a50-ca96c1bb84ac' User entered 'None (1)'	System	26 Sep 2020 23:46:59
	System	26 Sep 2020 23:46:59

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:46:57', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0176f49e-37ff-4a61-8a50-ca96c1bb84ac'	System	26 Sep 2020 23:46:59
User entered '26 Sep 2020 19:46'	System	26 Sep 2020 23:46:59

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 7'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:16', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'da5dea23-6cd6-437f-8ad8-716cdfe6d7b2'	System	28 Sep 2020 01:08:28
User entered 'None (1)'	System	28 Sep 2020 01:08:28



US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:19', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'da5dea23-6cd6-437f-8ad8-716cdfe6d7b2' User entered 'No (N)'	System	28 Sep 2020 01:08:28
	System	28 Sep 2020 01:08:28

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:21', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'da5dea23-6cd6-437f-8ad8-716cdfe6d7b2' User entered 'No (N)'	System	28 Sep 2020 01:08:28
	System	28 Sep 2020 01:08:28

US3412300

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:23', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'da5dea23-6cd6-437f-8ad8-716cdfe6d7b2'	System	28 Sep 2020 01:08:28
User entered 'None (1)'	System	28 Sep 2020 01:08:28

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:26', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'da5dea23-6cd6-437f-8ad8-716cdfe6d7b2'	System	28 Sep 2020 01:08:28
User entered '27 Sep 2020 21:08'	System	28 Sep 2020 01:08:28

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:51:08', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '328b75fe-68ee-49e1-a4d7-c446d4baabc5' User entered 'None (0)'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27



US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:51:11', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '328b75fe-68ee-49e1-a4d7-c446d4baabc5' User entered 'None (0)'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:51:12', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '328b75fe-68ee-49e1-a4d7-c446d4baabc5' User entered 'None (0)'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:51:14', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '328b75fe-68ee-49e1-a4d7-c446d4baabc5' User entered 'None (0)'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:51:16', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '328b75fe-68ee-49e1-a4d7-c446d4baabc5' User entered 'None (0)'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:51:17', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '328b75fe-68ee-49e1-a4d7-c446d4baabc5' User entered 'None (0)'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:51:21', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '328b75fe-68ee-49e1-a4d7-c446d4baabc5' User entered 'No (N)'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T09:51:24', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '328b75fe-68ee-49e1-a4d7-c446d4baabc5' User entered '21 Sep 2020 09:51'	System	21 Sep 2020 13:51:27
	System	21 Sep 2020 13:51:27

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '21 Sep 2020 09:35'	System	21 Sep 2020 13:19:30



**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '21 Sep 2020 12:05'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:29', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8486887f-d43c-4f01-86a0-9c2ecb1162cc' User entered 'None (0)'	System	21 Sep 2020 22:22:55
	System	21 Sep 2020 22:22:55

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:32', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8486887f-d43c-4f01-86a0-9c2ecb1162cc' User entered 'None (0)'	System	21 Sep 2020 22:22:55
	System	21 Sep 2020 22:22:55

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:35', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8486887f-d43c-4f01-86a0-9c2ecb1162cc' User entered 'None (0)'	System	21 Sep 2020 22:22:55
	System	21 Sep 2020 22:22:55

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:36', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8486887f-d43c-4f01-86a0-9c2ecb1162cc' User entered 'None (0)'	System	21 Sep 2020 22:22:55
	System	21 Sep 2020 22:22:55

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:39', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8486887f-d43c-4f01-86a0-9c2ecb1162cc' User entered 'None (0)'	System	21 Sep 2020 22:22:55
	System	21 Sep 2020 22:22:55

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:40', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8486887f-d43c-4f01-86a0-9c2ecb1162cc' User entered 'None (0)'	System	21 Sep 2020 22:22:55
	System	21 Sep 2020 22:22:55



US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:43', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8486887f-d43c-4f01-86a0-9c2ecb1162cc' User entered 'No (N)'	System	21 Sep 2020 22:22:55
	System	21 Sep 2020 22:22:55

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-21T18:22:49', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8486887f-d43c-4f01-86a0-9c2ecb1162cc' User entered '21 Sep 2020 18:22'	System	21 Sep 2020 22:22:55
	System	21 Sep 2020 22:22:55

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '21 Sep 2020 13:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 2'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:23', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '793504fc-555d-4432-8650-ec69cd33b530' User entered 'None (0)'	System	22 Sep 2020 21:05:44
	System	22 Sep 2020 21:05:44

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:26', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '793504fc-555d-4432-8650-ec69cd33b530' User entered 'None (0)'	System	22 Sep 2020 21:05:44
	System	22 Sep 2020 21:05:44

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:27', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '793504fc-555d-4432-8650-ec69cd33b530' User entered 'None (0)'	System	22 Sep 2020 21:05:44
	System	22 Sep 2020 21:05:44



US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:29', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '793504fc-555d-4432-8650-ec69cd33b530' User entered 'None (0)'	System	22 Sep 2020 21:05:44
	System	22 Sep 2020 21:05:44

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:31', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '793504fc-555d-4432-8650-ec69cd33b530' User entered 'None (0)'	System	22 Sep 2020 21:05:44
	System	22 Sep 2020 21:05:44

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:32', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '793504fc-555d-4432-8650-ec69cd33b530' User entered 'None (0)'	System	22 Sep 2020 21:05:44
	System	22 Sep 2020 21:05:44

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:35', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '793504fc-555d-4432-8650-ec69cd33b530' User entered 'No (N)'	System	22 Sep 2020 21:05:44
	System	22 Sep 2020 21:05:44

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-22T17:05:41', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '793504fc-555d-4432-8650-ec69cd33b530' User entered '22 Sep 2020 17:05'	System	22 Sep 2020 21:05:44
	System	22 Sep 2020 21:05:44

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 3'	System	21 Sep 2020 13:19:30



**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:24', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8936d145-6665-43f9-a3f3-8ad059ef106a' User entered 'None (0)'	System	23 Sep 2020 20:14:51
	System	23 Sep 2020 20:14:51

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:30', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8936d145-6665-43f9-a3f3-8ad059ef106a' User entered 'None (0)'	System	23 Sep 2020 20:14:51
	System	23 Sep 2020 20:14:51

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:32', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8936d145-6665-43f9-a3f3-8ad059ef106a' User entered 'None (0)'	System	23 Sep 2020 20:14:51
	System	23 Sep 2020 20:14:51

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:34', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8936d145-6665-43f9-a3f3-8ad059ef106a' User entered 'None (0)'	System	23 Sep 2020 20:14:51
	System	23 Sep 2020 20:14:51

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:36', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8936d145-6665-43f9-a3f3-8ad059ef106a' User entered 'None (0)'	System	23 Sep 2020 20:14:51
	System	23 Sep 2020 20:14:51

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:38', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8936d145-6665-43f9-a3f3-8ad059ef106a' User entered 'None (0)'	System	23 Sep 2020 20:14:51
	System	23 Sep 2020 20:14:51

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:42', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8936d145-6665-43f9-a3f3-8ad059ef106a' User entered 'No (N)'	System	23 Sep 2020 20:14:51
	System	23 Sep 2020 20:14:51

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-23T16:14:50', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8936d145-6665-43f9-a3f3-8ad059ef106a' User entered '23 Sep 2020 16:14'	System	23 Sep 2020 20:14:51
	System	23 Sep 2020 20:14:51



**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 4'	System	21 Sep 2020 13:19:30

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:14', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '98bec8a2-c345-4bd5-bfa8-f7e687dc6d37'	System	24 Sep 2020 18:07:30
User entered 'None (0)'	System	24 Sep 2020 18:07:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:16', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '98bec8a2-c345-4bd5-bfa8-f7e687dc6d37' User entered 'None (0)'	System	24 Sep 2020 18:07:30
	System	24 Sep 2020 18:07:30

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:17', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '98bec8a2-c345-4bd5-bfa8-f7e687dc6d37' User entered 'None (0)'	System	24 Sep 2020 18:07:30
	System	24 Sep 2020 18:07:30

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:19', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '98bec8a2-c345-4bd5-bfa8-f7e687dc6d37'	System	24 Sep 2020 18:07:30
User entered 'None (0)'	System	24 Sep 2020 18:07:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:20', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '98bec8a2-c345-4bd5-bfa8-f7e687dc6d37'	System	24 Sep 2020 18:07:30
User entered 'None (0)'	System	24 Sep 2020 18:07:30



US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:22', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '98bec8a2-c345-4bd5-bfa8-f7e687dc6d37'	System	24 Sep 2020 18:07:30
User entered 'None (0)'	System	24 Sep 2020 18:07:30

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:25', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '98bec8a2-c345-4bd5-bfa8-f7e687dc6d37'	System	24 Sep 2020 18:07:30
User entered 'No (N)'	System	24 Sep 2020 18:07:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-24T14:07:28', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '98bec8a2-c345-4bd5-bfa8-f7e687dc6d37'	System	24 Sep 2020 18:07:30
User entered '24 Sep 2020 14:07'	System	24 Sep 2020 18:07:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 5'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:57:03', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1ca6ec3d-9584-4da3-b788-f6d90558aef4' User entered 'None (0)'	System	25 Sep 2020 22:57:23
	System	25 Sep 2020 22:57:23

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:57:07', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1ca6ec3d-9584-4da3-b788-f6d90558aef4' User entered 'None (0)'	System	25 Sep 2020 22:57:23
	System	25 Sep 2020 22:57:23



US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:57:08', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1ca6ec3d-9584-4da3-b788-f6d90558aef4' User entered 'None (0)'	System	25 Sep 2020 22:57:23
	System	25 Sep 2020 22:57:23

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:57:10', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1ca6ec3d-9584-4da3-b788-f6d90558aef4' User entered 'None (0)'	System	25 Sep 2020 22:57:23
	System	25 Sep 2020 22:57:23

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:57:12', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1ca6ec3d-9584-4da3-b788-f6d90558aef4' User entered 'None (0)'	System	25 Sep 2020 22:57:23
	System	25 Sep 2020 22:57:23

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:57:14', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1ca6ec3d-9584-4da3-b788-f6d90558aef4' User entered 'None (0)'	System	25 Sep 2020 22:57:23
	System	25 Sep 2020 22:57:23

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:57:17', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1ca6ec3d-9584-4da3-b788-f6d90558aef4' User entered 'No (N)'	System	25 Sep 2020 22:57:23
	System	25 Sep 2020 22:57:23

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-25T18:57:20', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '1ca6ec3d-9584-4da3-b788-f6d90558aef4' User entered '25 Sep 2020 18:57'	System	25 Sep 2020 22:57:23
	System	25 Sep 2020 22:57:23

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:19:30



US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 6'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:47:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e34c22e2-40a5-461d-86fb-d1cbcab505a3' User entered 'None (0)'	System	26 Sep 2020 23:47:20
	System	26 Sep 2020 23:47:20

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:47:02', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e34c22e2-40a5-461d-86fb-d1cbcab505a3' User entered 'None (0)'	System	26 Sep 2020 23:47:20
	System	26 Sep 2020 23:47:20

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:47:03', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e34c22e2-40a5-461d-86fb-d1cbcab505a3' User entered 'None (0)'	System	26 Sep 2020 23:47:20
	System	26 Sep 2020 23:47:20

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:47:04', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e34c22e2-40a5-461d-86fb-d1cbcab505a3' User entered 'None (0)'	System	26 Sep 2020 23:47:20
	System	26 Sep 2020 23:47:20

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:47:06', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e34c22e2-40a5-461d-86fb-d1cbcab505a3' User entered 'None (0)'	System	26 Sep 2020 23:47:20
	System	26 Sep 2020 23:47:20

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:47:08', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e34c22e2-40a5-461d-86fb-d1cbcab505a3' User entered 'None (0)'	System	26 Sep 2020 23:47:20
	System	26 Sep 2020 23:47:20

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:47:11', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e34c22e2-40a5-461d-86fb-d1cbcab505a3'	System	26 Sep 2020 23:47:20
User entered 'No (N)'	System	26 Sep 2020 23:47:20



**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-26T19:47:14', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'e34c22e2-40a5-461d-86fb-d1cbcab505a3' User entered '26 Sep 2020 19:47'	System	26 Sep 2020 23:47:20
	System	26 Sep 2020 23:47:20

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	21 Sep 2020 13:19:30
User entered 'Day 7'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:29', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '55f0d4e9-dc81-4312-8859-0136d2504704' User entered 'None (0)'	System	28 Sep 2020 01:08:47
	System	28 Sep 2020 01:08:47

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:31', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '55f0d4e9-dc81-4312-8859-0136d2504704' User entered 'None (0)'	System	28 Sep 2020 01:08:47
	System	28 Sep 2020 01:08:47

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:33', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '55f0d4e9-dc81-4312-8859-0136d2504704'	System	28 Sep 2020 01:08:47
User entered 'None (0)'	System	28 Sep 2020 01:08:47

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:34', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '55f0d4e9-dc81-4312-8859-0136d2504704' User entered 'None (0)'	System	28 Sep 2020 01:08:47
	System	28 Sep 2020 01:08:47



**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:35', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '55f0d4e9-dc81-4312-8859-0136d2504704' User entered 'None (0)'	System	28 Sep 2020 01:08:47
	System	28 Sep 2020 01:08:47

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:36', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '55f0d4e9-dc81-4312-8859-0136d2504704' User entered 'None (0)'	System	28 Sep 2020 01:08:47
	System	28 Sep 2020 01:08:47

US3412300

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:03

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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:39', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '55f0d4e9-dc81-4312-8859-0136d2504704' User entered 'No (N)'	System	28 Sep 2020 01:08:47
	System	28 Sep 2020 01:08:47

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-09-27T21:08:43', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '55f0d4e9-dc81-4312-8859-0136d2504704'	System	28 Sep 2020 01:08:47
User entered '27 Sep 2020 21:08'	System	28 Sep 2020 01:08:47

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:03**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:19:30

**US3412300**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:17:57
User entered 'Yes (Y)'		28 Sep 2020 20:00:26

**US3412300**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:17:57
User entered '28 Sep 2020'		28 Sep 2020 20:00:26



**US3412300**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:17:57
User entered 'Contact Made (CONTACT MADE)'		28 Sep 2020 20:00:26

**US3412300**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:17:57
User entered empty.		28 Sep 2020 20:00:26

**US3412300**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:18:01
User entered 'Yes (Y)'		28 Sep 2020 20:00:31

**US3412300**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'I'	System	28 Sep 2020 20:00:31

**US3412300**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:18:07
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	05 Oct 2020 16:57:31

**US3412300**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:18:07
User entered '5 Oct 2020'	Mason Urban (b) (4) (b) (4)	05 Oct 2020 16:57:31

**US3412300**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:18:07
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	05 Oct 2020 16:57:31

**US3412300**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:18:07
User entered empty.	Mason Urban (b) (4) (b) (4)	05 Oct 2020 16:57:31



**US3412300**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 16:18:12
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	05 Oct 2020 16:57:23

**US3412300**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'I'	System	05 Oct 2020 16:57:23

**US3412300**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:08
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Oct 2020 15:11:54

**US3412300**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:08
User entered '13 Oct 2020'	Mason Urban (b) (4) (b) (4)	13 Oct 2020 15:11:54

**US3412300**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:08
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	13 Oct 2020 15:11:54

**US3412300**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:08
User entered empty.	Mason Urban (b) (4) (b) (4)	13 Oct 2020 15:11:54

**US3412300**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:12
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Oct 2020 15:11:59

**US3412300**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'I'	System	13 Oct 2020 15:11:59



**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:22
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Oct 2020 11:32:23

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:22
User entered '19 Oct 2020'	Steven Anderson (b) (4)	19 Oct 2020 11:32:23

US3412300

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:37:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:22
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	19 Oct 2020 11:32:23

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'VISIT3'	System	19 Oct 2020 11:32:23

US3412300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:32
User entered 'No (N)'	Steven Anderson (b) (4)	19 Oct 2020 11:32:28

US3412300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:32
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 11:32:28

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:32
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 11:32:28

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered empty.	System	19 Oct 2020 11:32:28



US3412300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:32
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 11:32:28

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:32
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 11:32:28

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:32
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 11:32:28

US3412300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:32
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 11:32:28

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered empty.	System	19 Oct 2020 11:32:28

US3412300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:32
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 11:32:28

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered empty.	System	19 Oct 2020 11:32:28

US3412300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:32
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 11:32:28



**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered empty.	System	19 Oct 2020 11:32:28

US3412300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:32
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 11:32:28

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered empty.	System	19 Oct 2020 11:32:28

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20

US3412300

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:50
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Oct 2020 15:11:51
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Oct 2020 11:32:38

US3412300

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:32:50
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Oct 2020 15:11:51
User entered '19 Oct 2020'	Steven Anderson (b) (4) (b) (4)	19 Oct 2020 11:32:38

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:33:06
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Oct 2020 11:32:54



US3412300

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:33:06
User entered '19 Oct 2020'	Steven Anderson (b) (4)	19 Oct 2020 11:32:54

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:33:06
User entered '07:20'	Steven Anderson (b) (4)	19 Oct 2020 11:32:54

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '19 Oct 2020 07:20'	System	19 Oct 2020 11:32:54

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:21:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:33:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Oct 2020 11:32:58

**US3412300**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered '1'	System	19 Oct 2020 11:32:58

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 64'	System	24 Aug 2020 12:26:10

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-10-24T04:55:14', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10827e8e-d3b4-4064-b909-9281afecfc0a' User entered 'No (N)'	System	24 Oct 2020 08:55:31
	System	24 Oct 2020 08:55:31

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Have you been exposed to someone with 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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-10-24T04:55:19', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10827e8e-d3b4-4064-b909-9281afecfc0a'	System	24 Oct 2020 08:55:31
User entered 'No (N)'	System	24 Oct 2020 08:55:31



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-10-24T04:55:29', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10827e8e-d3b4-4064-b909-9281afecfc0a' User entered '24 Oct 2020 04:55:29'	System	24 Oct 2020 08:55:31
	System	24 Oct 2020 08:55:31

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 12:26:10

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 12:26:10

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 71'	System	24 Aug 2020 12:26:10

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-10-31T07:40:05', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '790c4421-17fb-40c1-8e52-a78d99349143'	System	31 Oct 2020 11:40:28
User entered 'No (N)'	System	31 Oct 2020 11:40:28

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Have you been exposed to someone with 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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-10-31T07:40:18', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '790c4421-17fb-40c1-8e52-a78d99349143' User entered 'No (N)'	System	31 Oct 2020 11:40:28
	System	31 Oct 2020 11:40:28

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-10-31T07:40:25', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '790c4421-17fb-40c1-8e52-a78d99349143' User entered '31 Oct 2020 07:40:25'	System	31 Oct 2020 11:40:28
	System	31 Oct 2020 11:40:28

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 12:26:10



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 12:26:10

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered 'Day 78'	System	24 Aug 2020 12:26:10

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-11-07T14:47:54', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '90365d69-0333-4e80-ac97-aab3ecc9a129'	System	07 Nov 2020 19:48:09
User entered 'No (N)'	System	07 Nov 2020 19:48:09

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Have you been exposed to someone with 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 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-11-07T14:48:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '90365d69-0333-4e80-ac97-aab3ecc9a129'	System	07 Nov 2020 19:48:09
User entered 'No (N)'	System	07 Nov 2020 19:48:09

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB769943-FDFD-45BD-9BAC-22874E0A2FD6)', Time: '2020-11-07T14:48:08', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '90365d69-0333-4e80-ac97-aab3ecc9a129'	System	07 Nov 2020 19:48:09
User entered '07 Nov 2020 14:48:08'	System	07 Nov 2020 19:48:09

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 12:26:10

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:47
Data entry locked.	System	24 Aug 2020 12:26:10
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 12:26:10

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2020-12-23T05:59:26', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ffb18d9f-f7e2-4f02-9721-0b04c407ba6c' User entered 'No (N)'	System	23 Dec 2020 18:15:29
	System	23 Dec 2020 18:15:29



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2020-12-23T06:00:01', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ffb18d9f-f7e2-4f02-9721-0b04c407ba6c' User entered 'Yes (Y)'	System	23 Dec 2020 18:15:29
	System	23 Dec 2020 18:15:29

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Please 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2020-12-23T13:15:02', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ffb18d9f-f7e2-4f02-9721-0b04c407ba6c'	System	23 Dec 2020 18:15:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 18:15:29

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2020-12-23T13:15:19', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ffb18d9f-f7e2-4f02-9721-0b04c407ba6c' User entered '23 Dec 2020 13:15:19'	System	23 Dec 2020 18:15:29
	System	23 Dec 2020 18:15:29

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2020-12-30T02:37:40', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '7e60e022-c7ca-4d30-846f-b78f8c5639b8' User entered 'No (N)'	System	30 Dec 2020 07:38:00
	System	30 Dec 2020 07:38:00

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2020-12-30T02:37:44', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '7e60e022-c7ca-4d30-846f-b78f8c5639b8' User entered 'No (N)'	System	30 Dec 2020 07:38:00
	System	30 Dec 2020 07:38:00



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2020-12-30T02:37:56', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '7e60e022-c7ca-4d30-846f-b78f8c5639b8' User entered '30 Dec 2020 02:37:56'	System	30 Dec 2020 07:38:00
	System	30 Dec 2020 07:38:00

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-06T05:36:25', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '16be1d41-6aa7-4eeb-8b0b-456047c14254' User entered 'No (N)'	System	06 Jan 2021 10:36:52
	System	06 Jan 2021 10:36:52

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-06T05:36:27', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '16be1d41-6aa7-4eeb-8b0b-456047c14254'	System	06 Jan 2021 10:36:52
User entered 'Yes (Y)'	System	06 Jan 2021 10:36:52

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Please 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-06T05:36:32', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '16be1d41-6aa7-4eeb-8b0b-456047c14254'	System	06 Jan 2021 10:36:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 10:36:52

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-06T05:36:42', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '16be1d41-6aa7-4eeb-8b0b-456047c14254' User entered '06 Jan 2021 05:36:42'	System	06 Jan 2021 10:36:52
	System	06 Jan 2021 10:36:52



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-13T06:12:46', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '067de78f-55db-4298-9e17-4cd739b2f250'	System	13 Jan 2021 11:13:03
User entered 'No (N)'	System	13 Jan 2021 11:13:03

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-13T06:12:50', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '067de78f-55db-4298-9e17-4cd739b2f250'	System	13 Jan 2021 11:13:03
User entered 'No (N)'	System	13 Jan 2021 11:13:03

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-13T06:12:57', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '067de78f-55db-4298-9e17-4cd739b2f250' User entered '13 Jan 2021 06:12:57'	System	13 Jan 2021 11:13:03
	System	13 Jan 2021 11:13:03

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-20T13:19:57', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '03109be5-e3a0-4386-af29-d5a646ab8f97' User entered 'No (N)'	System	20 Jan 2021 18:20:11

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-20T13:20:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '03109be5-e3a0-4386-af29-d5a646ab8f97'	System	20 Jan 2021 18:20:11
User entered 'No (N)'	System	20 Jan 2021 18:20:11

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-20T13:20:07', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '03109be5-e3a0-4386-af29-d5a646ab8f97' User entered '20 Jan 2021 13:20:07'	System	20 Jan 2021 18:20:11
	System	20 Jan 2021 18:20:11

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-27T12:52:46', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0afb6d53-ef55-466d-85c8-97b287880b32' User entered 'No (N)'	System	27 Jan 2021 17:53:00
	System	27 Jan 2021 17:53:00



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-27T12:52:51', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0afb6d53-ef55-466d-85c8-97b287880b32'	System	27 Jan 2021 17:53:00
User entered 'No (N)'	System	27 Jan 2021 17:53:00

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-01-27T12:52:56', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '0afb6d53-ef55-466d-85c8-97b287880b32' User entered '27 Jan 2021 12:52:56'	System	27 Jan 2021 17:53:00
	System	27 Jan 2021 17:53:00

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-03T05:19:19', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '4a0ad8ce-5e57-43a5-8055-41dd8a728f1e' User entered 'No (N)'	System	03 Feb 2021 10:19:33
	System	03 Feb 2021 10:19:33

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-03T05:19:23', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '4a0ad8ce-5e57-43a5-8055-41dd8a728f1e' User entered 'No (N)'	System	03 Feb 2021 10:19:33
	System	03 Feb 2021 10:19:33

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-03T05:19:29', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '4a0ad8ce-5e57-43a5-8055-41dd8a728f1e' User entered '03 Feb 2021 05:19:29'	System	03 Feb 2021 10:19:33
	System	03 Feb 2021 10:19:33



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-10T05:21:21', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ee7cb367-9e24-42fd-8dd1-e7fd9675f2ba' User entered 'No (N)'	System	10 Feb 2021 10:21:39
	System	10 Feb 2021 10:21:39

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-10T05:21:26', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ee7cb367-9e24-42fd-8dd1-e7fd9675f2ba' User entered 'No (N)'	System	10 Feb 2021 10:21:39

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-10T05:21:35', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ee7cb367-9e24-42fd-8dd1-e7fd9675f2ba' User entered '10 Feb 2021 05:21:35'	System	10 Feb 2021 10:21:39

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-17T06:01:55', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '476c5b36-7328-4e0c-8ddb-711cc0b40054' User entered 'No (N)'	System	17 Feb 2021 11:02:08
	System	17 Feb 2021 11:02:08

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-17T06:01:58', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '476c5b36-7328-4e0c-8ddb-711cc0b40054' User entered 'No (N)'	System	17 Feb 2021 11:02:08
	System	17 Feb 2021 11:02:08

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-17T06:02:04', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '476c5b36-7328-4e0c-8ddb-711cc0b40054' User entered '17 Feb 2021 06:02:04'	System	17 Feb 2021 11:02:08
	System	17 Feb 2021 11:02:08

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-24T06:08:45-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6d1b1d5b-411d-41f2-84b5-f5e9c863eec7'	System	03 Mar 2021 03:10:13
User entered 'No (N)'	System	03 Mar 2021 03:10:13



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-24T06:08:48-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6d1b1d5b-411d-41f2-84b5-f5e9c863eec7'	System	03 Mar 2021 03:10:13
User entered 'No (N)'	System	03 Mar 2021 03:10:13

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-02-24T06:08:52-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '6d1b1d5b-411d-41f2-84b5-f5e9c863eec7' User entered '24 Feb 2021 11:08:52'	System	03 Mar 2021 03:10:13
	System	03 Mar 2021 03:10:13

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-03T08:08:37-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '5ed9465a-30b4-42f3-a6ba-e35df4855284' User entered 'No (N)'	System	03 Mar 2021 13:08:47
	System	03 Mar 2021 13:08:47

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-03T08:08:39-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '5ed9465a-30b4-42f3-a6ba-e35df4855284' User entered 'No (N)'	System	03 Mar 2021 13:08:47
	System	03 Mar 2021 13:08:47

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-03T08:08:42-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '5ed9465a-30b4-42f3-a6ba-e35df4855284' User entered '03 Mar 2021 08:08:42'	System	03 Mar 2021 13:08:47
	System	03 Mar 2021 13:08:47



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-10T04:25:34-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8f8a2d61-7d1d-498e-bfce-85f6e1080803'	System	10 Mar 2021 09:25:48
User entered 'No (N)'	System	10 Mar 2021 09:25:48

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-10T04:25:37-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8f8a2d61-7d1d-498e-bf6e-85f6e1080803'	System	10 Mar 2021 09:25:48
User entered 'No (N)'	System	10 Mar 2021 09:25:48

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-10T04:25:43-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '8f8a2d61-7d1d-498e-bfce-85f6e1080803' User entered '10 Mar 2021 04:25:43'	System	10 Mar 2021 09:25:48
	System	10 Mar 2021 09:25:48

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-17T09:24:21-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ed401849-f17b-46a0-8caa-4d6822030083' User entered 'No (N)'	System	17 Mar 2021 13:24:31
	System	17 Mar 2021 13:24:31

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-17T09:24:25-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ed401849-f17b-46a0-8caa-4d6822030083' User entered 'No (N)'	System	17 Mar 2021 13:24:31
	System	17 Mar 2021 13:24:31

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-17T09:24:28-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'ed401849-f17b-46a0-8caa-4d6822030083' User entered '17 Mar 2021 09:24:28'	System	17 Mar 2021 13:24:31
	System	17 Mar 2021 13:24:31

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-24T06:08:04-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10f81665-abe7-4002-8da1-0be71b641aa8'	System	24 Mar 2021 10:08:46
User entered 'No (N)'	System	24 Mar 2021 10:08:46



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-24T06:08:07-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10f81665-abe7-4002-8da1-0be71b641aa8'	System	24 Mar 2021 10:08:46
User entered 'No (N)'	System	24 Mar 2021 10:08:46

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-24T06:08:13-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '10f81665-abe7-4002-8da1-0be71b641aa8' User entered '24 Mar 2021 06:08:13'	System	24 Mar 2021 10:08:46
	System	24 Mar 2021 10:08:46

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-31T04:37:53-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a8d41c0b-20e8-40f0-aa5a-6ae2107cea7f' User entered 'No (N)'	System	31 Mar 2021 08:38:08
	System	31 Mar 2021 08:38:08

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-31T04:37:56-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a8d41c0b-20e8-40f0-aa5a-6ae2107cea7f' User entered 'No (N)'	System	31 Mar 2021 08:38:08
	System	31 Mar 2021 08:38:08

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-31T04:38:03-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'a8d41c0b-20e8-40f0-aa5a-6ae2107cea7f' User entered '31 Mar 2021 04:38:03'	System	31 Mar 2021 08:38:08
	System	31 Mar 2021 08:38:08



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-07T07:50:05-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '4d643c04-26fc-42bd-8298-58576f33cae4'	System	07 Apr 2021 11:50:31
User entered 'No (N)'	System	07 Apr 2021 11:50:31

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-07T07:50:18-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '4d643c04-26fc-42bd-8298-58576f33cae4'	System	07 Apr 2021 11:50:31
User entered 'No (N)'	System	07 Apr 2021 11:50:31

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-07T07:50:26-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '4d643c04-26fc-42bd-8298-58576f33cae4'	System	07 Apr 2021 11:50:31
User entered '07 Apr 2021 07:50:26'	System	07 Apr 2021 11:50:31

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-14T06:10:56-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'f3c70974-7ca3-48b6-889f-88abccf6a7a3'	System	14 Apr 2021 10:11:11
User entered 'No (N)'	System	14 Apr 2021 10:11:11

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-14T06:11:01-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'f3c70974-7ca3-48b6-889f-88abccf6a7a3'	System	14 Apr 2021 10:11:11
User entered 'No (N)'	System	14 Apr 2021 10:11:11

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-14T06:11:05-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: 'f3c70974-7ca3-48b6-889f-88abccf6a7a3'	System	14 Apr 2021 10:11:11
User entered '14 Apr 2021 06:11:05'	System	14 Apr 2021 10:11:11

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-21T10:25:27-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '38c228cb-de07-4345-b845-2f9a3f05e22b' User entered 'No (N)'	System	21 Apr 2021 14:25:39
	System	21 Apr 2021 14:25:39



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-21T10:25:28-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '38c228cb-de07-4345-b845-2f9a3f05e22b' User entered 'No (N)'	System	21 Apr 2021 14:25:39

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-21T10:25:33-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '38c228cb-de07-4345-b845-2f9a3f05e22b' User entered '21 Apr 2021 10:25:33'	System	21 Apr 2021 14:25:39
	System	21 Apr 2021 14:25:39

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-29T08:43:51-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '261872b8-2702-4d2c-8072-8c86ae5a8a3b' User entered 'No (N)'	System	29 Apr 2021 12:44:03
	System	29 Apr 2021 12:44:03

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

Have you been exposed to someone with 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 (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-29T08:43:53-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '261872b8-2702-4d2c-8072-8c86ae5a8a3b'	System	29 Apr 2021 12:44:03
User entered 'No (N)'	System	29 Apr 2021 12:44:03

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-04-29T08:43:56-04:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '261872b8-2702-4d2c-8072-8c86ae5a8a3b' User entered '29 Apr 2021 08:43:56'	System	29 Apr 2021 12:44:03
	System	29 Apr 2021 12:44:03



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:31:25



**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:31:25
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:31:25

**US3412300**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:37:03**

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 00:59:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-02T22:05:26-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '74d2d0ac-4c06-41bc-ae99-e3c019247d4f' User entered 'No (N)'	System	03 Mar 2021 03:10:32
	System	03 Mar 2021 03:10:32

**US3412300**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:59:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7A31444C-EE96-4A01-8316-8BD645D5EDE8)', Time: '2021-03-02T22:05:35-05:00', User OID: 'PatientReportedOutcome (US3412300)', ODM File OID: '74d2d0ac-4c06-41bc-ae99-e3c019247d4f' User entered '02 Mar 2021 22:05:35'	System	03 Mar 2021 03:10:32
	System	03 Mar 2021 03:10:32

**US3412300**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:53:50
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Dec 2020 15:51:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Nov 2020 14:33:26

**US3412300**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:53:50
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	02 Dec 2020 15:51:07
User entered '18 Nov 2020'	Mason Urban (b) (4)	20 Nov 2020 14:33:26



US3412300

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:53:50
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	02 Dec 2020 15:51:07
User entered 'Contact Not Made (CONTACT NOT MADE)'	Mason Urban (b) (4)	20 Nov 2020 14:33:26

US3412300

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:27:16
User closed query 'Please provide comments on why contact was not made' (Site from CRA).	(b) (4)	13 Jan 2021 21:27:14
Query 'Please provide comments on why contact was not made' answered with 'this has been updated to indicate why safety call visit was not completed' (Site from CRA).	Steven Anderson (b) (4)	15 Dec 2020 19:23:58
User entered 'Subject was in convalescent period during this safety call and therefor site was conducting daily safety calls which replaced any monthly phone calls.' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Dec 2020 19:23:20
User opened query 'Please provide comments on why contact was not made' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 17:24:23
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 16:53:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:53:50
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	02 Dec 2020 15:51:07
User entered 'Called multiple times, phone does not go to voicemail. Follow up with emergency contact'	Mason Urban (b) (4)	20 Nov 2020 14:33:26

US3412300

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:53:47
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Dec 2020 15:51:16

**US3412300**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:20
User entered 'I'	System	02 Dec 2020 15:51:16

US3412300

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:50:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Mason Urban (b) (4) (b) (4)	21 Dec 2020 14:31:43
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 14:19:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 14:19:38
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 14:19:38
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 19:13:32
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Dec 2020 19:13:32
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 17:09:39

**US3412300**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:50:29
User entered '21 Dec 2020' reason for change: Data Entry Error	Mason Urban (b) (4)	21 Dec 2020 14:31:43
User entered empty.	(b) (4) Steven Anderson (b) (4)	14 Dec 2020 17:09:39

**US3412300**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:50:29
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Mason Urban (b) (4) (b) (4)	21 Dec 2020 14:31:43
User entered empty.	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 17:09:39

US3412300

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:50:29
User entered empty; reason for change Data Entry Error	Mason Urban (b) (4)	21 Dec 2020 14:31:43
User entered 'SUBJECT WAS IN CONVALESCENT PERIOD DURING THIS SAFETY CALL AND THEREFOR SITE WAS CONDUCTING DAILY SAFETY CALLS WHICH REPLACED ANY MONTHLY PHONE CALLS.'	Melissa Fuson (b) (4)	21 Dec 2020 14:19:38
reason for change: Data Entry Error		
User entered empty.	Steven Anderson (b) (4)	14 Dec 2020 17:09:39



US3412300

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 19:50:35
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 14:20:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 14:20:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 14:20:06
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 19:13:37
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Dec 2020 19:13:37
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	14 Dec 2020 17:09:44

**US3412300**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User entered '1'	System	21 Dec 2020 14:20:06
User entered empty.	System	15 Dec 2020 19:13:37
User entered '1'	System	14 Dec 2020 17:09:44

**US3412300**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:40:26
User entered 'No (N)'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:20:21

**US3412300**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:40:26
User entered empty.	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:20:21

**US3412300**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:40:26
User entered empty.	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:20:21

US3412300

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:40:26
User entered 'PATIENT WAS IN OL PHASE AND NOT CALLED DUE TO SITE ERROR. SITE STAFF INSTRUCTED TO COMPLETE REGULAR SAFETY CALLS ALONGSIDE OPEN LABEL CALLS'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:20:21

**US3412300**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:40:31
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:20:29

**US3412300**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User entered 'I'	System	18 Feb 2021 15:20:29



**US3412300**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:41:48
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:20:48

**US3412300**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:41:48
User entered '18 Feb 2021'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:20:48

**US3412300**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:41:48
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:20:48

**US3412300**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:41:48
User entered empty.	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:20:48

**US3412300**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:41:52
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:20:52

**US3412300**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:10
User entered 'I'	System	18 Feb 2021 15:20:52

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:32
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:41:12

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:32
User entered '22 Mar 2021'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:41:12



**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:32
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:41:12

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'VISIT4'	System	07 Apr 2021 16:41:12

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:56
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:56
User entered '22 Mar 2021'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:56
User entered '08:11'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered '22 Mar 2021 08:11'	System	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:56
User entered '36.7' C	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:56
User entered 'Oral (Oral)'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:07



**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:56
User entered empty.	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:56
User entered '76'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'bpm'	System	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:56
User entered '15'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'breaths/min'	System	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:56
User entered '120'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'mmHg'	System	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:17:56
User entered '82'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:07



**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'mmHg'	System	07 Apr 2021 16:42:07

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23

US3412300

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:18:01
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:23

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:18:01
User entered empty.	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:23

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:18:07
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:53

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:18:07
User entered '22 Mar 2021'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:53

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:18:07
User entered '08:18'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:53



**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered '22 Mar 2021 08:18'	System	07 Apr 2021 16:42:53

US3412300

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:18:11
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 16:42:57

**US3412300**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:23
User entered 'I'	System	07 Apr 2021 16:42:57

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:37:03

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:46:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:07:36
User closed query 'Please reconcile and add the following required missing pages: 1. COVID Severity Assessment 2. Illness Day 1 3. Saliva Log ' (Site from CRA).		12 Nov 2020 01:09:39
Query 'Please reconcile and add the following required missing pages: 1. COVID Severity Assessment 2. Illness Day 1 3. Saliva Log ' answered with 'these have been added. ' (Site from CRA).	Jacob sekinger (b) (4)	09 Nov 2020 13:33:32
User opened query 'Please reconcile and add the following required missing pages: 1. COVID Severity Assessment 2. Illness Day 1 3. Saliva Log ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:01:18
User entered '04 Nov 2020'		05 Nov 2020 21:51:05

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:37:03**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:46:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:07:36
User entered '15:30'		05 Nov 2020 21:51:05

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:37:03**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:46:51
User entered '04 Nov 2020 15:30'	System	05 Nov 2020 21:51:05

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:37:03**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:46:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:07:36
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'		05 Nov 2020 21:51:05

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:37:03**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:46:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:07:36
User entered 'Yes (Y)'		05 Nov 2020 21:51:05



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:37:03

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User closed query 'Please verify that 04Nov2020 is first date subject experienced symptoms. Per CCG's and training provided to sites the first day recorded on symptom log is first date subject experienced symptoms. If subject experienced symptoms prior to this date the previous days must be added and the symptom days of previous entered lines update to reflect actual symptom day. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 01:09:59
Query 'Please verify that 04Nov2020 is first date subject experienced symptoms. Per CCG's and training provided to sites the first day recorded on symptom log is first date subject experienced symptoms. If subject experienced symptoms prior to this date the previous days must be added and the symptom days of previous entered lines update to reflect actual symptom day. ' answered with 'this has been updated. Subject first started experiencing problems on 02-nov-2020 site was unable to collect severity of any symptoms. this data has been added into the symptom log. ' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:12:47
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:11:23
User opened query 'Please verify that 04Nov2020 is first date subject experienced symptoms. Per CCG's and training provided to sites the first day recorded on symptom log is first date subject experienced symptoms. If subject experienced symptoms prior to this date the previous days must be added and the symptom days of previous entered lines update to reflect actual symptom day. ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:01:40
User entered 'Day 1 (Day 1)'		05 Nov 2020 21:51:22

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:37:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 12:11:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 12:11:54
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 12:11:54
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:51:22
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '0'		05 Nov 2020 21:51:22

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:37:03

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:38:03
User closed query 'Per CDM : It appears that O2 saturation was not collected. If not collected, please consider recording it as Not Done.' (Site from DM).		15 Jan 2021 15:59:34
Query 'Per CDM : It appears that O2 saturation was not collected. If not collected, please consider recording it as Not Done.' answered with 'UPDATED TO NOT DONE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:18:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:18:03
DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 21:25:53
User opened query 'Per CDM : It appears that O2 saturation was not collected. If not collected, please consider recording it as Not Done.' (Site from DM).		07 Jan 2021 15:19:24
DataPoint Verified.		17 Nov 2020 13:57:13
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	14 Jan 2021 16:18:03
User entered empty.	System	05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '37.7' C reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 12:11:54
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:51:22



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 12:11:54
User entered empty.		05 Nov 2020 21:51:22

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:11:23
User entered 'Day 2 (Day 2)'	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '05 Nov 2020'		06 Nov 2020 12:13:26



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '0'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '97'	(b) (4), (b) (6)	06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered '99.8' F	(b) (4), (b) (6)	06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 12:13:26

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:11:23
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '06 Nov 2020'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '0'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '95'	(b) (4), (b) (6)	06 Nov 2020 18:19:36



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered '98.8' F	(b) (4), (b) (6)	06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		06 Nov 2020 18:19:36

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:11:23
User entered 'Day 4 (Day 4)'	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '07 Nov 2020'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '0'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '95'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '98.1' F		09 Nov 2020 17:34:48



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:37:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User closed query 'please complete' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:22:45
DataPoint Verified.	(b) (4)	18 Nov 2020 20:22:37
Query 'please complete' answered with 'done' (Site from CRA).	Jacob sekinger (b) (4)	17 Nov 2020 17:14:17
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	17 Nov 2020 17:14:11
User opened query 'please complete' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 14:11:07
DataPoint Un-verified.	(b) (4)	17 Nov 2020 14:10:33
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered empty.	(b) (4)	09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:34:48



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:11:23
User entered 'Day 5 (Day 5)'	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:20:30
DataPoint Un-verified.		17 Nov 2020 14:13:26
DataPoint Verified.		17 Nov 2020 13:57:13
User entered '08 Nov 2020'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:07
DataPoint Un-verified.		17 Nov 2020 14:13:28
DataPoint Verified.		17 Nov 2020 13:57:13
User entered '0'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:23:10
DataPoint Un-verified.		17 Nov 2020 14:13:30
DataPoint Verified.		17 Nov 2020 13:57:13
User entered '95'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:16
DataPoint Un-verified.		17 Nov 2020 14:13:32
DataPoint Verified.		17 Nov 2020 13:57:13
User entered '99.9' F		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	19 Nov 2020 17:23:19
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 14:13:35
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:23:22
DataPoint Un-verified.		17 Nov 2020 14:13:39
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:25
DataPoint Un-verified.		17 Nov 2020 14:13:41
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:23:27
DataPoint Un-verified.		17 Nov 2020 14:13:42
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:29
DataPoint Un-verified.		17 Nov 2020 14:13:44
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:23:31
DataPoint Un-verified.		17 Nov 2020 14:13:46
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:36
DataPoint Un-verified.		17 Nov 2020 14:13:50
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:37:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:39
DataPoint Un-verified.		17 Nov 2020 14:13:53
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:41
DataPoint Un-verified.		17 Nov 2020 14:13:55
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:23:43
DataPoint Un-verified.		17 Nov 2020 14:13:56
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:23:46
DataPoint Un-verified.		17 Nov 2020 14:13:59
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:37:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:23:48
DataPoint Un-verified.		17 Nov 2020 14:14:09
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:23:50
DataPoint Un-verified.		17 Nov 2020 14:14:11
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:23:54
DataPoint Un-verified.		17 Nov 2020 14:14:13
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	9 Nov 2020 17:23:56
DataPoint Un-verified.		7 Nov 2020 14:14:15
DataPoint Verified.		7 Nov 2020 13:57:13
User entered 'None (None)'		9 Nov 2020 17:36:18

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:23:58
DataPoint Un-verified.		17 Nov 2020 14:14:23
DataPoint Verified.		17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:36:18

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:11:23
User entered 'Day 6 (Day 6)'	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '09 Nov 2020'		09 Nov 2020 17:37:27



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '0'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '95'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '99.1' F		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		09 Nov 2020 17:37:27

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:11:23
User entered 'Day 7 (Day 7)'	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '0'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '85'		10 Nov 2020 19:26:26



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '99.1' F		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		10 Nov 2020 19:26:26

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:37:03**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 1 (Day 1)'	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:37:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '02 Nov 2020'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:20:39
DataPoint Un-verified.	Steven Anderson (b) (4)	24 Nov 2020 21:54:23
User entered '0' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	24 Nov 2020 21:54:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '1'	Steven Anderson (b) (4)	10 Nov 2020 20:11:38
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:14:16
User closed query 'Per CDM : It appears that O2 saturation was not collected. If not collected, please consider recording it as Not Done.' (Site from DM).		15 Jan 2021 16:00:29
Query 'Per CDM : It appears that O2 saturation was not collected. If not collected, please consider recording it as Not Done.' answered with 'UPDATED TO NOT DONE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:31:41
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:31:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:31:31
User opened query 'Per CDM : It appears that O2 saturation was not collected. If not collected, please consider recording it as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:20:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:11:38

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	14 Jan 2021 16:31:31
User entered empty.	System	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	18 Nov 2020 20:22:11
User closed query 'Per source subject reported temp 100.1 - please consider updating from assessment not done to add' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:22:09
Query 'Per source subject reported temp 100.1 - please consider updating from assessment not done to add' answered with 'updated' (Site from CRA).	Jacob sekinger (b) (4)	17 Nov 2020 17:13:23
DataPoint Un-verified.	(b) (4)	17 Nov 2020 17:13:15
User entered '100.1' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	17 Nov 2020 17:13:15
User opened query 'Per source subject reported temp 100.1 - please consider updating from assessment not done to add' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 14:06:22
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38



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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:23:12
User closed query 'mild cough per source note? Please review source and update accordingly' (Site from CRA).	(b) (4)	18 Nov 2020 20:23:10
Query 'mild cough per source note? Please review source and update accordingly' answered with 'updated' (Site from CRA).	Jacob sekinger (b) (4)	17 Nov 2020 17:13:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	17 Nov 2020 17:13:15
User opened query 'mild cough per source note? Please review source and update accordingly' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 14:26:45
DataPoint Un-verified.	(b) (4)	17 Nov 2020 14:25:42
DataPoint Verified.	(b) (4)	17 Nov 2020 14:00:17
DataPoint Un-verified.	(b) (4)	17 Nov 2020 14:00:00
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:13:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	21 Dec 2020 14:13:14
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:21:04
User closed query 'Subject had headache per source. Please confirm and update as appropriate' (Site from CRA).		23 Nov 2020 17:51:52
Query 'Subject had headache per source. Please confirm and update as appropriate' answered with 'source does not indicate a headache on this day ' (Site from CRA).	Jacob sekinger (b) (4)	19 Nov 2020 17:46:33
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 17:46:24
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:27:16
DataPoint Verified.		19 Nov 2020 17:26:09
User opened query 'Subject had headache per source. Please confirm and update as appropriate' (Site from CRA).		19 Nov 2020 17:14:11
DataPoint Un-verified.		19 Nov 2020 17:13:54
DataPoint Verified.		17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38



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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 22:01:45
User closed query 'Please complete' (Site from CRA).	(b) (4)	08 Mar 2021 22:01:40
Query 'Please complete' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	26 Feb 2021 13:26:23
User entered 'None (None)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	26 Feb 2021 13:26:18
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 22:17:10
DataPoint Verified.	(b) (4)	23 Feb 2021 22:17:02
User opened query 'Please complete' (Site from CRA).	(b) (4)	23 Feb 2021 22:15:50
DataPoint Un-verified.	(b) (4)	23 Feb 2021 22:15:28
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:21:04
User closed query 'Subject had congestion per source. Please confirm and update as appropriate' (Site from CRA).		24 Nov 2020 22:20:52
Query 'Subject had congestion per source. Please confirm and update as appropriate' answered with 'source does not indicate this condition on this specific day ' (Site from CRA).	Jacob sekinger (b) (4)	19 Nov 2020 17:46:59
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:27:19
DataPoint Verified.		19 Nov 2020 17:26:09
User opened query 'Subject had congestion per source. Please confirm and update as appropriate' (Site from CRA).		19 Nov 2020 17:14:27
DataPoint Un-verified.		19 Nov 2020 17:13:56
DataPoint Verified.		17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	
User closed query 'Subject had "sniffles" per source. Please consider which symptom this would fall under and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 22:01:52
Query 'Subject had "sniffles" per source. Please consider which symptom this would fall under and update as appropriate' answered with 'updated' (Site from CRA).		08 Mar 2021 22:01:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	26 Feb 2021 13:26:27
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	26 Feb 2021 13:26:18
	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 22:17:12
DataPoint Verified.		23 Feb 2021 22:17:02
User opened query 'Subject had "sniffles" per source. Please consider which symptom this would fall under and update as appropriate' (Site from CRA).		23 Feb 2021 22:16:47
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 22:21:04
User closed query 'Subject had "sniffles" per source. Please confirm and update as appropriate' (Site from CRA).		24 Nov 2020 22:20:50
Query 'Subject had "sniffles" per source. Please confirm and update as appropriate' answered with 'source does not indicate this condition on this specific day ' (Site from CRA).	Jacob sekinger (b) (4)	19 Nov 2020 17:47:03
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:27:21
DataPoint Verified.		19 Nov 2020 17:26:09

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User opened query 'Subject had "sniffles" per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:14:56
DataPoint Un-verified.		19 Nov 2020 17:14:45
DataPoint Verified.		17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38



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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:37:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:17:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 14:14:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	21 Dec 2020 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:38

**US3412300**

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**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:37:03**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 2 (Day 2)'	Steven Anderson (b) (4)	10 Nov 2020 20:11:56

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:37:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '03 Nov 2020'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:11:56

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered '0' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '1'	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	07 Dec 2020 17:41:05
User entered empty.	System	10 Nov 2020 20:11:56

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered '100.1' F reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:37:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:37:10
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:41:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered empty.	Steven Anderson (b) (4)	10 Nov 2020 20:11:56
	(b) (4)	

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:44:53



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 13:57:13
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 21:44:53

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:37:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:23:43
User closed query '95% per source? Please review source and update accordingly' (Site from CRA).		18 Nov 2020 20:23:41
Query '95% per source? Please review source and update accordingly' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	17 Nov 2020 17:10:22
User entered '95' reason for change: Data Entry Error	Jacob sekinger (b) (4)	17 Nov 2020 17:10:16
User opened query '95% per source? Please review source and update accordingly' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 14:30:24
DataPoint Un-verified.		17 Nov 2020 14:29:45
DataPoint Verified.		17 Nov 2020 13:57:13
User entered '93'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '100.0' F		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:37:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		11 Nov 2020 21:44:53

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '12 Nov 2020'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '0'		12 Nov 2020 20:35:16



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '95'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '98.7' F		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:37:03**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		12 Nov 2020 20:35:16

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User closed query 'Please add 14 Nov 2020, 15 Nov 2020, 16 Nov 2020, 17 Nov 2020 - MUST UPDATE EACH DAY IN REAL TIME PLEASE!' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:25:42
Query 'Please add 14 Nov 2020, 15 Nov 2020, 16 Nov 2020, 17 Nov 2020 - MUST UPDATE EACH DAY IN REAL TIME PLEASE!' answered with 'added. ' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:47:07
User opened query 'Please add 14 Nov 2020, 15 Nov 2020, 16 Nov 2020, 17 Nov 2020 - MUST UPDATE EACH DAY IN REAL TIME PLEASE!' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:28:22
DataPoint Verified.		17 Nov 2020 13:57:13
User entered '13 Nov 2020'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '0'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '98'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	13 Nov 2020 15:41:05



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered '97.7' F		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 15:41:05



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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 15:41:05



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:37:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:57:13
User entered 'None (None)'		13 Nov 2020 17:31:35
DataPoint activated with code reason code Data required.		13 Nov 2020 17:30:16
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4) (b) (4)	13 Nov 2020 15:41:05

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data	(b) (4)	
required.	Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not	(b) (4)	
required.	(b) (4), (b) (6)	13 Nov 2020 17:34:50
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:40:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 16:40:31
User entered '14 Nov 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:50
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 17:31:35
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

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Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
DataPoint activated with code reason code Data required.	Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:50
User entered '0'		13 Nov 2020 17:31:35

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '95' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:34:50
User entered empty.		13 Nov 2020 17:31:35

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	System	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '97.1' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:42:12
User entered '97.6' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:50
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35



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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:50
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:34:50
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:50
User entered empty.		13 Nov 2020 17:31:35



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:50
User entered empty.		13 Nov 2020 17:31:35

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:50
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:37:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:40:31
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:38:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data	(b) (4)	
required.	Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not	(b) (4)	
required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:44:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 16:44:04
User entered '15 Nov 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 17:31:35
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
DataPoint activated with code reason code Data required.	Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered '0'		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '95' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:56
User entered empty.	System	13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '98.7' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4)	13 Nov 2020 17:34:56
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:31:35



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:37:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:44:04
DataPoint activated with code reason code Data required.	(b) (4)	19 Nov 2020 16:40:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Nov 2020 17:34:56
User entered empty.		13 Nov 2020 17:31:35

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 15 (Day 15)'	Jacob sekinger (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '16 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '0'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '95'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '98.7' F	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:37:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:45:28

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User entered 'Day 16 (Day 16)'	Jacob sekinger (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '17 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '0'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '95'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:37:03**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User entered '%'	System	19 Nov 2020 16:46:51



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered '97.6' F	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:37:03**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:37:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:47:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:09
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 16:46:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:49:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:02
User entered '04 Nov 2020'		06 Nov 2020 12:13:54

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:37:03**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:49:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:02
User entered 'Yes (Y)'		06 Nov 2020 12:13:54

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:37:03

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:49:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:02
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).		17 Nov 2020 13:58:52
User closed query 'Please verify as central lab provided positive results. AE log to be updated to reflect COVID-19 AE since illness results were positive.		12 Nov 2020 01:10:42
' (Site from CRA).		
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'will updated AE form. Patient tested positive. ' (Site from System).	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:07:27
Query 'Please verify as central lab provided positive results. AE log to be updated to reflect COVID-19 AE since illness results were positive.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:07:08
' answered with 'pt tested positive for covid. ' (Site from CRA).		
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	09 Nov 2020 13:06:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:06:31
User opened query 'Please verify as central lab provided positive results. AE log to be updated to reflect COVID-19 AE since illness results were positive.	(b) (4), (b) (6)	08 Nov 2020 21:02:32
' (Site from CRA).		
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 13:43:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 13:43:49
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 13:43:49

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EAB) (1725)

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**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:37:03**

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 12:13:54
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 12:13:54

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:49:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:02
User entered '04 Nov 2020'		06 Nov 2020 12:13:54

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:37:03**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:49:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:02
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'		06 Nov 2020 12:13:54

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:37:03**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:49:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:02
User entered empty.		06 Nov 2020 12:13:54



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:37:03**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:49:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:02
User entered 'No (N)'		06 Nov 2020 12:13:54

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:37:03**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:49:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:02
User entered empty.		06 Nov 2020 12:13:54

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:37:03**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:49:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:02
User entered empty.		06 Nov 2020 12:13:54

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:37:03**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:49:57
User entered '1'	System	09 Nov 2020 13:06:31
User entered '0'	System	06 Nov 2020 13:43:49

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Did the subject have Respiratory Rates  \$\geq\$  30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Did the subject have Heart Rate  \$\geq\$  125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User closed query 'Per DM CLR: Please note that there is no corresponding AE recorded for this COVID-19 Assessment data. Please review AE#1 (START DATE 02 NOV 2020 - END DATE 04 NOV 2020) and reconcile dates and update to record the AE as applicable. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 08:29:20
Query 'Per DM CLR: Please note that there is no corresponding AE recorded for this COVID-19 Assessment data. Please review AE#1 (START DATE 02 NOV 2020 - END DATE 04 NOV 2020) and reconcile dates and update to record the AE as applicable. Otherwise, provide clarification.' answered with 'SUB STATED OXYGEN SATURATION OF 85% FOR A FEW MOMENTS RETURNED TO 96% LATER IN DAY' (Site from DM).		25 Mar 2021 18:56:24
User opened query 'Per DM CLR: Please note that there is no corresponding AE recorded for this COVID-19 Assessment data. Please review AE#1 (START DATE 02 NOV 2020 - END DATE 04 NOV 2020) and reconcile dates and update to record the AE as applicable. Otherwise, provide clarification.' (Site from DM).		19 Mar 2021 09:03:54
DataPoint Verified.		19 Nov 2020 18:32:14
User closed query 'Please complete start date, end date, and oxygen saturation fields below this' (Site from CRA).		19 Nov 2020 18:32:10
Query 'Please complete start date, end date, and oxygen saturation fields below this' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	19 Nov 2020 17:37:24
User opened query 'Please complete start date, end date, and oxygen saturation fields below this' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:29:30
DataPoint Un-verified.		19 Nov 2020 17:29:10

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
User closed query 'Please reconcile as symptom log notes 85% on 10Nov2020' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:29:03
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:29:01
Query 'Please reconcile as symptom log notes 85% on 10Nov2020' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	19 Nov 2020 16:48:59
DataPoint Un-verified.	Jacob sekinger (b) (4)	19 Nov 2020 16:48:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:48:40
User opened query 'Please reconcile as symptom log notes 85% on 10Nov2020' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 03:26:38
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4)	09 Nov 2020 13:12:51

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:32:16
DataPoint Un-verified.	Jacob sekinger (b) (4)	19 Nov 2020 17:37:16
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 17:37:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:32:19
DataPoint Un-verified.	Jacob sekinger (b) (4)	19 Nov 2020 17:37:16
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 17:37:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51



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Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:32:22
DataPoint Un-verified.	Jacob sekinger (b) (4)	19 Nov 2020 17:37:16
User entered '85' reason for change: Data Entry Error	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 17:37:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

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Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

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**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51



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**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51



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Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51



**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:37:03

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51

**US3412300**

**Folder: Covid-19 Assessment 04 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:38:30
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:12:51



US3412300

Folder: Covid-19 Assessment 04 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:37:03

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:50:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User closed query 'Please update to No. Will only be Yes if subject has second incidence of symptoms' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:05:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:05:18
Query 'Please update to No. Will only be Yes if subject has second incidence of symptoms' answered with 'updated.' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	18 Nov 2020 13:30:33
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	18 Nov 2020 13:30:26
User opened query 'Please update to No. Will only be Yes if subject has second incidence of symptoms' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 14:39:49
User entered 'Yes (Y)'		05 Nov 2020 21:43:12

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	09 Nov 2020 13:32:46
	(b) (4)	

US3412300

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:37:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:23:12
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06,08,10,12,17NOV2020 is recorded under Illness Visit Day 3,5,7,9,14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		09 Dec 2020 06:55:22
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06,08,10,12,17NOV2020 is recorded under Illness Visit Day 3,5,7,9,14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'PER PPD SOURCE DOCUMENT IN FOLDER FOR ACCESSION 1F60AG2 GENERATED REPORT DATE 04-DEC-2020 SAMPLES WERE RECEIVED' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	07 Dec 2020 20:50:24
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06,08,10,12,17NOV2020 is recorded under Illness Visit Day 3,5,7,9,14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 07:10:41
User entered '6 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

US3412300

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:37:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:07:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:33:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 13:33:02
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	09 Nov 2020 13:33:02
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:32:46
User entered empty.	Jacob sekinger (b) (4)	09 Nov 2020 13:32:46
	(b) (4)	

US3412300

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:37:03

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08NOV2020 is recorded under Illness visit day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08NOV2020 is recorded under Illness visit day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'per preclarus sample day 5 was shipped, processed, and reported in preclarus' (Site from DM).	Steven Anderson (b) (4)	15 Apr 2021 15:56:28
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08NOV2020 is recorded under Illness visit day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 05:31:32
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is recorded under Illness Visit Day 21 in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).		12 Apr 2021 07:30:10
DataPoint Verified.		09 Apr 2021 12:38:01

US3412300

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:37:03

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is recorded under Illness Visit Day 21 in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'this has been updated. saliva was collected by the subject on 08-nov-20 however was not submitted until 24-nov-20' (Site from DM). DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 17:28:59
	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 17:28:54
User entered '08 Nov 2020' reason for change: Data Entry Error DataPoint Verified.	Steven Anderson (b) (4) (b) (4)	07 Apr 2021 17:28:54
	(b) (4), (b) (6)	07 Apr 2021 15:27:53
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is recorded under Illness Visit Day 21 in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you.' (Site from DM).		02 Apr 2021 06:51:15
User closed query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 24NOV2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF. Thanks' (Site from DM).		26 Mar 2021 05:54:17
Query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 24NOV2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF. Thanks' answered with 'updated' (Site from DM). DataPoint Un-verified.		23 Mar 2021 18:48:02
		23 Mar 2021 18:47:52
User entered '24 Nov 2020' reason for change: Data Entry Error		23 Mar 2021 18:47:52
User opened query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 24NOV2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF. Thanks ' (Site from DM).		23 Mar 2021 06:59:32

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EAB) (1725)

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**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered '08 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:07:07
User entered empty.	Jacob sekinger (b) (4)	09 Nov 2020 13:32:46

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

US3412300

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:37:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:07:30
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:33:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 13:33:02
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	09 Nov 2020 13:33:02
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:32:46
User entered empty.	Jacob sekinger (b) (4)	09 Nov 2020 13:32:46
	(b) (4)	

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered '10 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:07:30
User entered empty.	(b) (4)	
	Jacob sekinger (b) (4)	09 Nov 2020 13:32:46
	(b) (4)	

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

US3412300

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:37:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	13 Jan 2021 21:23:12
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	13 Nov 2020 15:41:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:33:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 13:33:02
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	09 Nov 2020 13:33:02
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:32:46
User entered empty.	Jacob sekinger (b) (4)	09 Nov 2020 13:32:46
	(b) (4)	

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered '12 Nov 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	13 Nov 2020 15:41:32
User entered empty.	(b) (4)	
	Jacob sekinger (b) (4)	09 Nov 2020 13:32:46
	(b) (4)	

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46



US3412300

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:37:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Nov 2020 14:59:31
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:33:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 13:33:02
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	09 Nov 2020 13:33:02
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:32:46
User entered empty.	Jacob sekinger (b) (4)	09 Nov 2020 13:32:46
	(b) (4)	

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered '17 Nov 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	23 Nov 2020 14:59:31
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

US3412300

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:37:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 20:25:56
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:33:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 13:33:02
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:33:02
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:32:46
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered '24 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 20:25:47
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

US3412300

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:37:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:23:12
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 13:51:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 13:51:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 13:51:12
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 20:25:56
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 20:25:56
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:33:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 13:33:02
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:33:02
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:32:46
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46

**US3412300**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:23:12
User entered '02 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 13:51:12
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:32:46



**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:11
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:01:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:11
User entered '04 Nov 2020'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:01:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:11
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:01:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered 'SICKD1'	System	10 Nov 2020 20:01:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:02:52

US3412300

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	10 Nov 2020 20:03:00
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	10 Nov 2020 20:03:00
User entered '04 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:03:00
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	10 Nov 2020 20:02:52
User entered '04 Oct 2020'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered '15:44'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered '04 Nov 2020 15:44'	System	10 Nov 2020 20:03:00
User entered '04 Oct 2020 15:44'	System	10 Nov 2020 20:02:52



**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered '168.5' cm	Steven Anderson (b) (4)	10 Nov 2020 20:02:52
DataPoint set to visible.	(b) (4) System	10 Nov 2020 20:01:52

US3412300

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered '120.2' kg	Steven Anderson (b) (4)	10 Nov 2020 20:02:52
DataPoint set to visible.	(b) (4) System	10 Nov 2020 20:01:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered '37.7' C	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered 'Oral (Oral)'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered '84'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered 'bpm'	System	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered '16'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:02:52



**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered 'breaths/min'	System	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered '142'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered 'mmHg'	System	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:40:58
User entered '80'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered 'mmHg'	System	10 Nov 2020 20:02:52

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42

US3412300

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
User closed query 'Per source, physical exam was within normal limits. Please confirm if performed and update as appropriate' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:26:46
Query 'Per source, physical exam was within normal limits. Please confirm if performed and update as appropriate' answered with 'was performed and within normal limits. wrong comment was chosen' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 21:26:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 14:18:47
User opened query 'Per source, physical exam was within normal limits. Please confirm if performed and update as appropriate' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:23:51
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	01 Dec 2020 16:39:21
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:41:03
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:03:13



US3412300

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:26:44
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	21 Dec 2020 14:18:39
User entered '4 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 14:18:39
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	21 Dec 2020 14:17:41
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	01 Dec 2020 16:39:21
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	01 Dec 2020 16:39:21
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:41:03
User entered '04 Nov 2020'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:03:13

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:37:03**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:41:08
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:03:24

**US3412300**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:41:08
User entered '04 Nov 2020'	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:03:24

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:37:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:28:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:51:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 10:14:34
Query 'Data is required. Please complete.' answered with 'subject has not presented for this visit yet' (Site from System).	Steven Anderson (b) (4)	11 Nov 2020 17:15:01
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 17:14:47
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 17:14:47
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	09 Nov 2020 13:29:23

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:37:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:28:09
User entered '2 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 13:51:53
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	11 Nov 2020 17:14:47
User entered '04 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:29:23

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:37:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:28:10
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 13:51:53
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	11 Nov 2020 17:14:47
User entered 'Clinic (Clinic)'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:29:23

**US3412300**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User entered 'SICKD28'	System	02 Dec 2020 13:51:53
User entered empty.	System	11 Nov 2020 17:14:47
User entered 'SICKD28'	System	09 Nov 2020 13:29:23

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:53:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 10:14:29
Query 'Data is required. Please complete.' answered with 'subject has not presented for this visit yet' (Site from System).	Steven Anderson (b) (4)	11 Nov 2020 17:15:42
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 17:15:37
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 17:15:37
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	09 Nov 2020 13:31:11



US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:24
User entered '2 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:53:42
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 17:15:37
User entered '04 Nov 2020'	Jacob sekinger (b) (4)	09 Nov 2020 13:31:11

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:26
User entered '08:25' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:53:42
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 17:15:37
User entered '15:44'	Jacob sekinger (b) (4)	09 Nov 2020 13:31:11

**US3412300**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User entered '2 Dec 2020 08:25'	System	02 Dec 2020 13:53:42
User entered empty.	System	11 Nov 2020 17:15:37
User entered '04 Nov 2020 15:44'	System	09 Nov 2020 13:31:11

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:31
User entered '172' cm reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:53:42
DataPoint set to visible.	System	02 Dec 2020 13:51:53
DataPoint set to invisible.	System	11 Nov 2020 17:14:47
User entered '168.5' cm	Jacob sekinger (b) (4)	09 Nov 2020 13:31:11
DataPoint set to visible.	System	09 Nov 2020 13:29:23

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Dec 2020 13:53:56
User entered '122.7' kg reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 13:53:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Dec 2020 13:53:42
User entered '122.737.0' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 13:53:42
DataPoint set to visible.	System	02 Dec 2020 13:51:53
DataPoint set to invisible.	System	11 Nov 2020 17:14:47
User entered '120.2' kg	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:31:11
DataPoint set to visible.	System	09 Nov 2020 13:29:23

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:37
User entered '37.0' C reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 13:53:42
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	11 Nov 2020 17:15:37
User entered '37.7' C	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:31:11

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:39
User entered 'Oral (Oral)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:53:42
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 17:15:37
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	09 Nov 2020 13:31:11

**US3412300**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:41
User entered empty.	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:31:11



US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:45
User entered '68' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:53:42
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 17:15:37
User entered '84'	Jacob sekinger (b) (4)	09 Nov 2020 13:31:11

**US3412300**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User entered 'bpm'	System	02 Dec 2020 13:53:42
User entered empty.	System	11 Nov 2020 17:15:37
User entered 'bpm'	System	09 Nov 2020 13:31:11

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:47
User entered '18' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:53:42
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 17:15:37
User entered '16'	Jacob sekinger (b) (4)	09 Nov 2020 13:31:11

**US3412300**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User entered 'breaths/min'	System	02 Dec 2020 13:53:42
User entered empty.	System	11 Nov 2020 17:15:37
User entered 'breaths/min'	System	09 Nov 2020 13:31:11

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:49
User entered '124' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 13:53:42
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	11 Nov 2020 17:15:37
User entered '142'	Jacob sekinger (b) (4) (b) (4)	09 Nov 2020 13:31:11

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User entered 'mmHg'	System	02 Dec 2020 13:53:42
User entered empty.	System	11 Nov 2020 17:15:37
User entered 'mmHg'	System	09 Nov 2020 13:31:11

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:27:52
User entered '80' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:53:42
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 17:15:37
User entered '80'	Jacob sekinger (b) (4)	09 Nov 2020 13:31:11

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User entered 'mmHg'	System	02 Dec 2020 13:53:42
User entered empty.	System	11 Nov 2020 17:15:37
User entered 'mmHg'	System	09 Nov 2020 13:31:11



**US3412300**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28

**US3412300**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:22:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:54:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Nov 2020 10:14:25
Query 'Data is required. Please complete.' answered with 'subject has not presented for this visit yet' (Site from System).	Steven Anderson (b) (4)	11 Nov 2020 17:15:59
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 17:15:56
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 17:15:56
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	09 Nov 2020 13:31:25

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:22:06
User entered '2 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:54:39
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 17:15:56
User entered '04 Nov 2020'	Jacob sekinger (b) (4)	09 Nov 2020 13:31:25

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:37:03

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:08:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:54:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Nov 2020 10:39:48
Query 'Data is required. Please complete.' answered with 'day 28 has not occurred yet. ' (Site from System).	Jacob sekinger (b) (4)	19 Nov 2020 16:55:13
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:54:36
User entered empty; reason for change Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:54:36
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	09 Nov 2020 13:32:16

US3412300

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:37:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:08:01
User entered '2 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	02 Dec 2020 13:54:54
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 NOV 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the illness visit Day 1 in PPD Central lab. 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)	23 Nov 2020 10:30:22
User entered empty; reason for change Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 16:54:36
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 NOV 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the illness visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'this should not have been added. ' (Site from DM).	Jacob sekinger (b) (4)	19 Nov 2020 16:54:09
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 NOV 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the illness visit Day 1 in PPD Central lab. 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)	12 Nov 2020 10:44:43
User entered '04 Nov 2020'	Jacob sekinger (b) (4)	09 Nov 2020 13:32:16

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:46:11
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:33:04

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:46:11
User entered '14 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:33:04



**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:46:11
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:33:04

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 16:33:04

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:03**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:46:28
User entered '14 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:33:25

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:03**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:36:48
User entered '0'		18 Mar 2021 18:07:19
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:45:04

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:37:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:46:28
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	14 Jan 2021 16:33:37
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	14 Jan 2021 16:33:37
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	14 Jan 2021 16:33:25
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:33:25

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:03**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:36:48
User closed query 'Amendment 6 - please complete' (Site from CRA).		19 Mar 2021 16:36:43
Query 'Amendment 6 - please complete' answered with 'UPDATED' (Site from CRA).		18 Mar 2021 18:07:27
User entered 'Amendment 6 or later (Amendment 6 or later)'		18 Mar 2021 18:07:19
User opened query 'Amendment 6 - please complete' (Site from CRA).		08 Mar 2021 21:53:03
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:45:04

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:03**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:46:28
User entered '14 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:33:25

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:37:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:46:28
User entered 'Placebo (Placebo)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:33:25



US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:37:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:46:28
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 12:41:09
User entered 'Placebo (Placebo)' reason for change:	Melissa Fuson (b) (4)	14 Jan 2021 16:33:37
Data Entry Error	(b) (4)	
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:33:25

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:03**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:46:28
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 12:41:09
User entered 'Placebo (Placebo)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:33:25

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:03**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:46:28
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:33:25

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:03**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered '1'	System	14 Jan 2021 16:33:37
User entered empty.	System	14 Jan 2021 16:33:25

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered '1'	System	14 Jan 2021 16:33:37
User entered empty.	System	14 Jan 2021 16:33:25

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '170.2' cm	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '120.9' kg	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:37:03**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered '41.73565'	System	14 Jan 2021 16:40:44
DataPoint set to visible.	System	14 Jan 2021 16:33:37



US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '170.2' cm	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '120.9' kg	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:37:03**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered '41.73565'	System	14 Jan 2021 16:40:44
DataPoint set to visible.	System	14 Jan 2021 16:33:37

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User accepted default value 'Pre-Dose (PREDOSE)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '14 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '08:03'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered '14 Jan 2021 08:03'	System	14 Jan 2021 16:40:44



**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '36.5' C	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '82'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'bpm'	System	14 Jan 2021 16:40:44

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '18'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'breaths/min'	System	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '132'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44



**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'mmHg'	System	14 Jan 2021 16:40:44

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '76'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'mmHg'	System	14 Jan 2021 16:40:44

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '170.2' cm	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '120.9' kg	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:37:03**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered '41.73565'	System	14 Jan 2021 16:40:44
DataPoint set to visible.	System	14 Jan 2021 16:33:37

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User accepted default value 'Post-Dose (POSTDOSE)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44



**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '14 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '08:58'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered '14 Jan 2021 08:58'	System	14 Jan 2021 16:40:44

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '98.4' F	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '68'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'bpm'	System	14 Jan 2021 16:40:44



**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '16'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'breaths/min'	System	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '124'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'mmHg'	System	14 Jan 2021 16:40:44

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:02
User entered '84'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:40:44

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'mmHg'	System	14 Jan 2021 16:40:44

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:08
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:43:13

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:08
User entered '14 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:43:13



**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:21
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:43:39

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:21
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:43:39

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:03

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)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:21
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:43:39

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'mRNA-1273'	System	14 Jan 2021 16:43:39
DataPoint set to visible.	System	14 Jan 2021 16:33:37

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:21
User entered '14 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:43:39

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:21
User entered '08:22'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:43:39

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered '14 Jan 2021 08:22'	System	14 Jan 2021 16:43:39

US3412300

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:21
User entered 'Left Arm (LEFT ARM)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:43:39



**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
DataPoint Verified.		23 Feb 2021 21:49:21
User entered 'ONCE'	System	14 Jan 2021 16:43:39

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 16:43:39

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:42
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:44:32

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:42
User entered '14 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:44:32

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:42
User entered '08:15'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:44:32

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered '14 Jan 2021 08:15'	System	14 Jan 2021 16:44:32

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:37:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:47
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:44:50

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:47
User entered '14 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:44:50



**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:37:03**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:47
User entered '08:10'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:44:50

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:37:03**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered '14 Jan 2021 08:10'	System	14 Jan 2021 16:44:50

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:49:51
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:44:57

**US3412300**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered '1'	System	14 Jan 2021 16:44:57

**US3412300**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:50:56
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	21 Jan 2021 15:59:20

**US3412300**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:50:56
User entered '21 Jan 2021'	Mason Urban (b) (4) (b) (4)	21 Jan 2021 15:59:20

**US3412300**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:50:56
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	21 Jan 2021 15:59:20

**US3412300**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:50:56
User entered empty.	Mason Urban (b) (4) (b) (4)	21 Jan 2021 15:59:20



**US3412300**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:51:00
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	21 Jan 2021 15:59:25

**US3412300**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'I'	System	21 Jan 2021 15:59:25

**US3412300**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered '1'	System	21 Jan 2021 15:59:25
DataPoint set to visible.	System	21 Jan 2021 15:59:25

**US3412300**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:52:03
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:25:43

**US3412300**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:52:03
User entered '11 Feb 2021'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:25:43

**US3412300**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:52:03
User entered 'Clinic (Clinic)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:25:43

**US3412300**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'OLD29'	System	11 Feb 2021 21:25:43

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User accepted default value 'Pre-Dose (PREDOSE)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40



**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '11 Feb 2021'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '07:25'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered '11 Feb 2021 07:25'	System	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '36.5' C	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '78'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40



**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'bpm'	System	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '14'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'breaths/min'	System	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '140'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'mmHg'	System	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '70'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'mmHg'	System	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User accepted default value 'Post-Dose (POSTDOSE)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40



**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '11 Feb 2021'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '08:36'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered '11 Feb 2021 08:36'	System	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '98.4' F	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '77'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40



**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'bpm'	System	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '16'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'breaths/min'	System	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '124'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'mmHg'	System	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:53:52
User entered '78'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'mmHg'	System	11 Feb 2021 21:27:40

**US3412300**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:54:03
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:53



**US3412300**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:54:03
User entered '11 Feb 2021'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:27:53

**US3412300**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:54:16
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:28:23

**US3412300**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:54:16
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:28:23

**US3412300**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

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)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:54:16
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:28:23

**US3412300**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'mRNA-1273'	System	11 Feb 2021 21:28:23
DataPoint set to visible.	System	21 Jan 2021 15:59:25

**US3412300**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:54:16
User entered '11 Feb 2021'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:28:23

**US3412300**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:54:16
User entered '08:03'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:28:23

**US3412300**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered '11 Feb 2021 08:03'	System	11 Feb 2021 21:28:23



**US3412300**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:54:16
User entered 'Left Arm (LEFT ARM)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:28:23

**US3412300**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
DataPoint Verified.		23 Feb 2021 21:54:16
User entered 'ONCE'	System	11 Feb 2021 21:28:23

**US3412300**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:03**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 21:28:23

**US3412300**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:54:21
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	11 Feb 2021 21:28:30

**US3412300**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'I'	System	11 Feb 2021 21:28:30

**US3412300**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:55:14
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:18:51

**US3412300**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:55:14
User entered '18 Feb 2021'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:18:51

**US3412300**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:55:14
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:18:51



**US3412300**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:03**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:55:14
User entered empty.	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:18:51

**US3412300**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:55:17
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	18 Feb 2021 15:18:57

**US3412300**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:19
User entered 'I'	System	18 Feb 2021 15:18:57

**US3412300**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	07 Apr 2021 15:21:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 14:56:40

**US3412300**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:21:05
User entered '22 Mar 2021'		29 Mar 2021 14:56:40

**US3412300**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:05
User entered 'Clinic (Clinic)'		29 Mar 2021 14:56:40

**US3412300**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'OLD57'	System	29 Mar 2021 14:56:40

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:36
User entered 'Yes (Y)'		29 Mar 2021 14:57:24



**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:36
User entered '22 Mar 2021'		29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:36
User entered '08:11'		29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered '22 Mar 2021 08:11'	System	29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:36
User entered '36.7' C		29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:36
User entered 'Oral (Oral)'		29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:36
User entered empty.		29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:36
User entered '76'		29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'bpm'	System	29 Mar 2021 14:57:24



**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:36
User entered '15'		29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'breaths/min'	System	29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:36
User entered '120'		29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'mmHg'	System	29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:36
User entered '82'		29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered 'mmHg'	System	29 Mar 2021 14:57:24

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10

**US3412300**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:03**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10



**US3412300**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:03**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:40
User entered 'No (N)'		29 Mar 2021 14:57:30

**US3412300**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:40
User entered empty.		29 Mar 2021 14:57:30

**US3412300**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:47
User entered 'Yes (Y)'		29 Mar 2021 14:57:55

**US3412300**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:47
User entered '22 Mar 2021'		29 Mar 2021 14:57:55

**US3412300**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:47
User entered '08:18'		29 Mar 2021 14:57:55

**US3412300**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:10
User entered '22 Mar 2021 08:18'	System	29 Mar 2021 14:57:55

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:37:03**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:30:13
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:44:27
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:29:14

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
Reviewed for Safety.	(b) (4)	08 Dec 2020 14:55:08
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 14:55:04
DataPoint Verified.		17 Nov 2020 14:48:37
Reviewed for Safety.		11 Nov 2020 19:05:20
User entered 'USA-US061-2020-mRNA-1273-P301000008'	System	11 Nov 2020 19:04:56
User entered 'New'	(b) (4), (b) (6)	11 Nov 2020 19:04:56



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 20:50:16
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	27 Jan 2021 14:34:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Jan 2021 14:34:10
	(b) (4)	
Data point term sent to Coder	System	27 Jan 2021 14:33:24
Coding entries removed.	Melissa Fuson (b) (4)	27 Jan 2021 14:32:26
	(b) (4)	
User entered 'SYMPTOMATIC COVID -19' reason for change: Data Entry Error	Melissa Fuson (b) (4)	27 Jan 2021 14:32:26
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	14 Jan 2021 16:35:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Jan 2021 16:35:56
	(b) (4)	
Data point term sent to Coder	System	14 Jan 2021 16:20:27
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 16:20:26
	(b) (4)	
Coding entries removed.	Melissa Fuson (b) (4)	14 Jan 2021 16:20:26
	(b) (4)	
User entered 'COVID -19' reason for change: Data Entry Error	Melissa Fuson (b) (4)	14 Jan 2021 16:20:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:14
User closed query 'Per p. 36 of CRF Completion Guidelines V2, please update term to SymptomaticCOVID-19' (Site from CRA).		18 Nov 2020 20:31:12
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 17:18:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 17:18:52
	(b) (4)	
Data point term sent to Coder	System	17 Nov 2020 17:18:27
Query 'Per p. 36 of CRF Completion Guidelines V2, please update term to SymptomaticCOVID-19' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	17 Nov 2020 17:18:21
	(b) (4)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Jacob sekinger (b) (4)	17 Nov 2020 17:18:11
	(b) (4)	
User entered 'symptomatic COVID -19' reason for change: Data Entry Error	Jacob sekinger (b) (4)	17 Nov 2020 17:18:11
	(b) (4)	
User opened query 'Per p. 36 of CRF Completion Guidelines V2, please update term to SymptomaticCOVID-19' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 14:58:02
Query 'per p. 51 of CRF guidelines v 2, please update term to Symptomatic COVID-19' canceled (Site from CRA).		17 Nov 2020 14:50:14
DataPoint Un-verified.		17 Nov 2020 14:48:44
DataPoint Verified.		17 Nov 2020 14:48:37
User opened query 'per p. 51 of CRF guidelines v 2, please update term to Symptomatic COVID-19' (Site from CRA).		17 Nov 2020 14:48:19
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 18:33:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 18:33:40
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 18:32:49
User entered 'COVID -19'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
User closed query 'please update to YES - illness visit and telehealth visitscompleted' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 20:31:21 18 Nov 2020 20:31:19
Query 'please update to YES - illness visit and telehealth visitscompleted' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	17 Nov 2020 17:18:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	17 Nov 2020 17:18:11
User opened query 'please update to YES - illness visit and telehealth visitscompleted' (Site from CRA). Query 'Per p. 36 of CRF Completion Guidelines V2, please update term to SymptomaticCOVID-19' canceled (Site from CRA). User opened query 'Per p. 36 of CRF Completion Guidelines V2, please update term to SymptomaticCOVID-19' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 14:51:55 17 Nov 2020 14:51:18 17 Nov 2020 14:51:05
DataPoint Verified.		17 Nov 2020 14:48:41
DataPoint Un-verified.		17 Nov 2020 14:48:37
DataPoint Verified.		17 Nov 2020 14:48:32
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	17 Nov 2020 14:48:29 10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 04:34:48
User closed query 'Please reconcile as COVID pages note that symptoms began on 02Nov2020' (Site from CRA).		20 Nov 2020 04:34:47
Query 'Please reconcile as COVID pages note that symptoms began on 02Nov2020' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	19 Nov 2020 17:03:51
	(b) (4)	
DataPoint Un-verified.	Jacob sekinger (b) (4)	19 Nov 2020 17:02:36
	(b) (4)	
User entered '2 Nov 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 17:02:36
	(b) (4)	
User opened query 'Please reconcile as COVID pages note that symptoms began on 02Nov2020' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:43:53
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered '4 Nov 2020'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 18:31:52



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:05:23
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). DataPoint Un-verified.	System	11 Dec 2020 15:31:08
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:31:08
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). DataPoint Verified.	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:31:00
User entered 'Yes (Y)'	System	11 Dec 2020 15:31:00
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:59:50
User closed query 'please confirm stop date. Stop date should be date when no symptoms present - subject only had symptoms on 02 Nov 2020 per source.' (Site from CRA).		22 Feb 2021 05:38:20
Query 'please confirm stop date. Stop date should be date when no symptoms present - subject only had symptoms on 02 Nov 2020 per source.' answered with 'date amended to 04Nov, which is when patient resolved all symptoms per source.' (Site from CRA).	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 22:18:00
User entered '04 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 22:16:49
User opened query 'please confirm stop date. Stop date should be date when no symptoms present - subject only had symptoms on 02 Nov 2020 per source.' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 19:45:28
User closed query 'please review source and reconcile with AE source log - negative PCR on 2 Dec 2020 - should stop date be updated?' (Site from CRA).		21 Jan 2021 19:55:00
Query 'please review source and reconcile with AE source log - negative PCR on 2 Dec 2020 - should stop date be updated?' answered with 'UPDATED TO 02-DEC-2020 PER NOTE ON SOURCE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:15:13
User entered '02 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:14:48
DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 20:13:29
User opened query 'please review source and reconcile with AE source log - negative PCR on 2 Dec 2020 - should stop date be updated?' (Site from CRA).		13 Jan 2021 20:12:43
DataPoint Verified.		15 Dec 2020 17:05:24
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		11 Dec 2020 20:30:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'this has been updated' (Site from Safety). DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:31:22
	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:31:00
User entered '17 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:31:00
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). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	17 Nov 2020 15:15:03
	(b) (4), (b) (6) (b) (4)	17 Nov 2020 14:48:37
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please update the date of resolution to the date when the symptoms resolved.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:46:47
User opened query 'PV Query: Please update the date of resolution to the date when the symptoms resolved.' (Site from Safety).		30 Dec 2020 20:52:05
User entered empty.	System	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	



**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	

US3412300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered empty.	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	



**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered 'Not Related (NOT RELATED)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered 'Not Related (NOT RELATED)'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	

US3412300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:51:01
User closed query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with [study drug] from none to not applicable. [Study drug stopped prior to SAE]' (Site from Safety).		21 Nov 2020 00:12:06
Query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with [study drug] from none to not applicable. [Study drug stopped prior to SAE]' answered with 'updated. ' (Site from Safety).	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 17:03:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 17:02:36
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 20:31:43
User opened query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with [study drug] from none to not applicable. [Study drug stopped prior to SAE]' (Site from Safety).		17 Nov 2020 15:15:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered 'None (NONE)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered 'I'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 18:31:52
	(b) (4)	

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered '0'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

US3412300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:05:46
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		11 Dec 2020 20:30:18
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'this has been updated' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:31:29
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:31:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:31:00
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:51:05
DataPoint Un-verified.	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 17:02:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 17:02:36
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 15:16:22
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52



**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:48:37
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

US3412300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 04:04:19
User closed query 'Please update narrative with all info through negative PCR on 2 Dec 2020' (Site from CRA).		24 Feb 2021 04:04:17
Query 'Please update narrative with all info through negative PCR on 2 Dec 2020' answered with 'UPDATED NARRATIVE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:30:44
User entered 'SUBJECT WAS EXPOSED TO COWORKERS WHO TESTED POSITIVE FOR COVID 26OCT2020. SUBJECT REPORTED MILD DRY COUGH, HEADACHES, CONGESTION, FEVER (100.1 F) AND SNIFFLES ON 02 NOV2020. EVERY SYMPTOM RESOLVED BY 03-NOV-2020 EXCEPT A FEVER . ON 04-NOV-2020 THE FEVER HAD BROKE AND WAS <38.0 DEGREES CELSIUS. THERE WAS NO TREATMENT ADMINISTERED BY THE SUBJECT. REPORTED ON VISIT NOTES THAT SUBJECT DOIN WELL WITGH NO REPORTS OF ANY SYMPTOMS ON 05-06-07-08-NOV-2020. 09-NOV-2020 SUBJECT INFORMED OF TEST RESULTS AND DAY 28 VISIT SCHEDULED FOR 02-DEC-2020 AT 0700. SUBJECT REPORTS FEELING WELL WITH NO C/O SYMPTOMS. 10-NOV-2020 SUBJECT REPORTS FEELING WELL WITH NO NEW SYMPTOMS BUT STATED OXYGEN SATURATION WAS 85% WAS ONLY FOR A FEW MOMENTS. SUBJECT OXYGEN SATURATION DURING PHONE CALL WAS 96%. FROM 11-NOV-2020 TO 17-NOV-2020 SUBJECT FEELING WELL WITH NO SYMPTOMS TO REPORT. STOPPED TELEMEDICINE VISIT CALLS. SUBJECT REPORTED FOR DAY 28 VISIT ON 02-DEC-2020 AND TOLERATED ALL PROCEDURES. AE CLOSED' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:30:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Please update narrative with all info through negative PCR on 2 Dec 2020' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 20:16:05
DataPoint Verified.		13 Jan 2021 20:15:21
User closed query 'PV Query: Per case narrative, subject experienced headache on 02 Nov 2020. However, symptom log (day 1) indicated headaches as None. Kindly consider updating symptom logs with this information. ' (Site from Safety). Query 'PV Query: Per case narrative, subject experienced headache on 02 Nov 2020. However, symptom log (day 1) indicated headaches as None. Kindly consider updating symptom logs with this information. ' answered with 'updated the symptom log for headache to mild' (Site from Safety).		02 Jan 2021 14:38:39
User opened query 'PV Query: Per case narrative, subject experienced headache on 02 Nov 2020. However, symptom log (day 1) indicated headaches as None. Kindly consider updating symptom logs with this information. ' (Site from Safety).		22 Dec 2020 17:55:03
User closed query 'PV Query: Per case narrative, subject experienced a mild fever on 04 NOV, and headache on 02 Nov, however symptom logs do not report the same. Kindly consider updating symptom logs with this information.' (Site from Safety).	Melissa Fuson (b) (4)	21 Dec 2020 14:15:41
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:39:18
		08 Dec 2020 14:55:26
		08 Dec 2020 14:55:21

US3412300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Per case narrative, subject experienced a mild fever on 04 NOV, and headache on 02 Nov, however symptom logs do not report the same. Kindly consider updating symptom logs with this information.' answered with 'The narrative has been updated to better explain the symptoms and their onset. site symptom log was also updated to portray the symptoms prior to their illness visit.' (Site from Safety).	Steven Anderson (b) (4)	07 Dec 2020 17:47:35
User entered 'SUBJECT WAS EXPOSED TO COWORKERS WHO TESTED POSITIVE FOR covid 26OCT2020. SUBJECT REPORTED MILD DRY COUGH, HEADACHES, congestion, FEVER (100.1 F) AND SNIFFLES ON 02 NOV2020. Every symptom resolved by 03-nov-2020 except a fever . On 04-Nov-2020 the fever had broke and was <38.0 degrees Celsius. THERE WAS NO TREATMENT ADMINISTERED BY THE SUBJECT.' reason for change: Data Entry Error	Steven Anderson (b) (4)	07 Dec 2020 17:46:43
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'subject did not administer any treatment. narrative updated to indicate so' (Site from Safety).	Steven Anderson (b) (4)	07 Dec 2020 17:43:23
DataPoint Un-verified.	Steven Anderson (b) (4)	07 Dec 2020 17:42:49
User entered 'SUBJECT WAS EXPOSED TO COWORKERS WHO TESTED POSITIVE FOR 26OCT2020. SUBJECT REPORTED MILD DRY COUGH, HEADACHES, FEVER (100.1 F) AND SNIFFLES. ON 02 NOV2020 WITH A MILD FEVER. NO SYMPTOMS EXCEPT FEVER AT VISIT ON 04NOV2020. There was no treatment administered by the subject.' reason for change: Data Entry Error	Steven Anderson (b) (4)	07 Dec 2020 17:42:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per case narrative, subject experienced a mild fever on 04 NOV, and headache on 02 Nov, however symptom logs do not report the same. Kindly consider updating symptom logs with this information.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 19:08:01
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).		04 Dec 2020 19:06:55
User closed query 'Per p. 39 of Completion Guidelines, please complete narrative with all pertinent information' (Site from CRA).		23 Nov 2020 17:51:11
DataPoint Verified.		23 Nov 2020 17:51:08
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		21 Nov 2020 00:12:16
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		21 Nov 2020 00:12:13
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, symptoms log.' (Site from Safety).		21 Nov 2020 00:11:58
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'updated.' (Site from Safety).	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 17:03:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated. ' (Site from Safety).	Jacob sekinger (b) (4)	19 Nov 2020 17:03:15
Query 'PV Query: Please complete the Covid-19 Assessments tab, symptoms log. ' answered with 'updated. ' (Site from Safety).	Jacob sekinger (b) (4)	19 Nov 2020 17:03:08
Query 'Per p. 39 of Completion Guidelines, please complete narrative with all pertinent information' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	19 Nov 2020 17:02:57
User entered 'subject was exposed to coworkers who tested positive for 26Oct2020. subject reported mild dry cough, headaches, fever (100.1 F) and sniffles. on 02 Nov2020 with a mild fever. No symptoms except fever at visit on 04Nov2020.' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Nov 2020 17:02:36
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 15:16:07
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).		17 Nov 2020 15:15:47
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, symptoms log. ' (Site from Safety).		17 Nov 2020 15:15:17
User opened query 'Per p. 39 of Completion Guidelines, please complete narrative with all pertinent information' (Site from CRA).		17 Nov 2020 14:57:24
DataPoint Un-verified.		17 Nov 2020 14:52:26
DataPoint Verified.		17 Nov 2020 14:48:37

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 18:31:52

**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 18:31:52



**US3412300**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 17:18:11
User entered '0'	System	10 Nov 2020 18:31:52

US3412300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:37:03

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:30:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:44:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:19
DataPoint Un-verified.	Melissa Fuson (b) (4)	21 Dec 2020 15:49:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	21 Dec 2020 15:49:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:03:53
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	31 Aug 2020 17:52:09

US3412300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:37:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 21:25:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:23
	(b) (4)	
Data point term sent to Coder	System	21 Dec 2020 15:51:47
User entered 'INFLUENZA VACCINE'	Melissa Fuson (b) (4)	21 Dec 2020 15:51:01
	(b) (4)	

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered 'GENERAL HEALTH'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered '0.5'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered 'mL (mL)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01



**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered 'once (ONCE)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered '07 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered '0'	Melissa Fuson (b) (4)	21 Dec 2020 15:51:01
	(b) (4)	

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered '7 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01



**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:25:11
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 15:51:01

**US3412300**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:37:03**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:44:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 22:00:56
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	05 Mar 2021 15:13:43

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'USA-US061-2020-MRNA-1273-P301000008'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 14:58:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'		11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gregory'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gottschlich'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Cincinnati'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '45242'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:12:37
DataPoint Verified.		17 Nov 2020 14:58:25
User entered 'US'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Mar 2021 00:29:10
User entered '5'	System	22 Dec 2020 17:55:25
User entered '4'	System	11 Dec 2020 20:30:45
User entered '3'	System	08 Dec 2020 14:57:11
User entered '2'	System	21 Nov 2020 00:12:51
User entered '1'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'USA-US061-2020-MRNA-1273-P301000008'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 14:58:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gregory'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gottschlich'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Cincinnati'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '45242'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:12:37
DataPoint Verified.		17 Nov 2020 14:58:25
User entered 'US'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Mar 2021 00:29:10
User entered '5'	System	22 Dec 2020 17:55:25
User entered '4'	System	11 Dec 2020 20:30:45
User entered '3'	System	08 Dec 2020 14:57:11
User entered '2'	System	21 Nov 2020 00:12:51
User entered '1'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
User entered '11/Nov/2020 19:07'	System	11 Nov 2020 19:07:22

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:37:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:12:37
DataPoint Verified.		17 Nov 2020 14:58:25
User entered '1'		11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 14:58:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:07:14
User entered 'USA-US061-2020-MRNA-1273-P301000008'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gregory'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gottschlich'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Cincinnati'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '45242'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:12:37
DataPoint Verified.		17 Nov 2020 14:58:25
User entered 'US'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Mar 2021 00:29:10
User entered '5'	System	22 Dec 2020 17:55:25
User entered '4'	System	11 Dec 2020 20:30:45
User entered '3'	System	08 Dec 2020 14:57:11
User entered '2'	System	21 Nov 2020 00:12:51
User entered '1'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:51:19
User entered '20/Nov/2020 19:12'	System	21 Nov 2020 00:12:51

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:37:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
Reviewed for Safety.	(b) (4)	11 Dec 2020 20:30:28
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:51:19
User entered '1'		21 Nov 2020 00:12:51

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'USA-US061-2020-MRNA-1273-P301000008'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 14:58:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 14:58:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gregory'		11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gottschlich'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Cincinnati'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '45242'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:12:37
DataPoint Verified.		17 Nov 2020 14:58:25
User entered 'US'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Mar 2021 00:29:10
User entered '5'	System	22 Dec 2020 17:55:25
User entered '4'	System	11 Dec 2020 20:30:45
User entered '3'	System	08 Dec 2020 14:57:11
User entered '2'	System	21 Nov 2020 00:12:51
User entered '1'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:59:10
User entered '08/Dec/2020 08:57'	System	08 Dec 2020 14:57:11

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:37:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	08 Mar 2021 21:59:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:30:28
User entered 'I'		08 Dec 2020 14:57:11

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'USA-US061-2020-MRNA-1273-P301000008'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 14:58:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gregory'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gottschlich'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Cincinnati'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '45242'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:12:37
DataPoint Verified.		17 Nov 2020 14:58:25
User entered 'US'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Mar 2021 00:29:10
User entered '5'	System	22 Dec 2020 17:55:25
User entered '4'	System	11 Dec 2020 20:30:45
User entered '3'	System	08 Dec 2020 14:57:11
User entered '2'	System	21 Nov 2020 00:12:51
User entered '1'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (4)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:59:10
User entered '11/Dec/2020 20:30'	System	11 Dec 2020 20:30:45

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:37:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:59:10
Reviewed for Safety.		22 Dec 2020 17:55:17
User entered 'I'		11 Dec 2020 20:30:45



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'USA-US061-2020-MRNA-1273-P301000008'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gregory'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gottschlich'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Cincinnati'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '45242'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:12:37
DataPoint Verified.		17 Nov 2020 14:58:25
User entered 'US'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Mar 2021 00:29:10
User entered '5'	System	22 Dec 2020 17:55:25
User entered '4'	System	11 Dec 2020 20:30:45
User entered '3'	System	08 Dec 2020 14:57:11
User entered '2'	System	21 Nov 2020 00:12:51
User entered '1'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (5)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:59:10
User entered '22/Dec/2020 12:55'	System	22 Dec 2020 17:55:25



US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:37:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:59:10
User entered 'I'		22 Dec 2020 17:55:25

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'USA-US061-2020-MRNA-1273-P301000008'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4)	17 Nov 2020 14:58:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'No (N)'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gregory'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Gottschlich'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered 'Cincinnati'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:58:25
Reviewed for Safety.		11 Nov 2020 19:07:14
User entered '45242'	System	11 Nov 2020 19:04:56

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:12:37
DataPoint Verified.		17 Nov 2020 14:58:25
User entered 'US'	System	11 Nov 2020 19:07:22

**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Mar 2021 00:29:10
User entered '5'	System	22 Dec 2020 17:55:25
User entered '4'	System	11 Dec 2020 20:30:45
User entered '3'	System	08 Dec 2020 14:57:11
User entered '2'	System	21 Nov 2020 00:12:51
User entered '1'	System	11 Nov 2020 19:07:22



**US3412300**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (6)**

**Generated On: 11 Aug 2021 22:37:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:28:22
User entered '17/Mar/2021 20:29'	System	18 Mar 2021 00:29:10

US3412300

Folder: SAE USA-US061-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 22:37:03

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:28:22
User entered 'I'		18 Mar 2021 00:29:10